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-2022 IRB-Regulations of Operation-2022	文件名稱 Title	資料與安全性監測計畫管理程序書 SOP for Data and Safety Monitoring Plan
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	13	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.修改 5.1 流程圖之相關文件。 2. Revised relevant documents of 5.1 Flow Chart	20160318
D	12	1.修改參考文件 3.1 人體試驗管理辦法版本。 1. Revised the version of reference 3.1 Regulations on Human Trials	20170709
D	12	依本院規定，於 2019 年 05 月 17 日重新審視本文件，內容無須修改。 This file was re-examined on 17 May 2019 to comply with our hospital policies. No revision was needed.	20170709
D	12	依本院規定，於 2020 年 09 月 20 日重新審視本文件，內容無須修改。 This file was re-examined on 20 September 2020 to comply with our hospital policies. No revision was needed.	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
E	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”.	20220920

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。

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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-2022 IRB-Regulations of Operation-2022	文件名稱 Title	資料與安全性監測計畫管理程序書 SOP for Data and Safety Monitoring Plan	
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

1. Purpose

本管理程序書是要讓審查委員及承辦人員了解審查『資料與安全性監測計畫』（Data and Safety Monitoring Plan，以下簡稱 DSMP）及『資料與安全性監測委員會』（Data and Safety Monitoring Board，以下簡稱 DSMB）之原則與標準作業程序，以落實受試者保護安全。

The purpose of this SOP is to provide reviewers and staff members with guidelines and standard operating procedures for Data and Safety Monitoring Plan (DSMP) and Data and Safety Monitoring Board (DSMB) to ensure adequate protection is in place for the trial subjects.

2.適用範圍

2. Scope

審查委員評估研究計畫之潛在風險之後，如果認定風險較高於最低風險，得要求計畫委託人與主持人必須提出適切的 DSMP，以保障受試者之安全與數據之可信與完整。可能會被委員會決議要求提出 DSMP 的情況，例如：(1)人體試驗管理辦法第二條規範之「新藥品、新醫療器材於辦理查驗登記前，或醫療機構將新醫療技術，列入常規醫療處置項目前」之人體試驗；(2)不論有無委託廠商，但經本委員會會議討論後，認定風險較高之案件；(3)研究對象為特殊易受傷害群體受試者，不論有無委託廠商，經本委員會會議個案討論後，決議之案件。

Should the reviewers deem the potential risks associated with the research greater than minimal, they have the authority to request a DSMP from the sponsor and the principal investigator to ensure subject safety and data validity and integrity. A DSMP may be required at the discretion of the IRB when: (1) a research involves human trials in accordance with Article 2 of Regulations on Human Trials: “A human trial research shall be conducted prior to the registration of a new drug or medical device or before a medical care institution lists a new medical technology as a regular medical

disposition item."; (2) the risk level is determined to be high by the IRB regardless of the presence or absence of a sponsor; (3) trials in an IRB-approved protocol that include a case study containing subjects considered vulnerable research population, regardless of the presence or absence of a sponsor.

3.參考文件

3. Reference

3.1 人體試驗管理辦法(民國 105 年 04 月 14 日衛生福利部衛部醫字第 1051662154 號令修正發布)。

3.1 Regulations on Human Trials (Ministry of Health and Welfare, amended and promulgated on 14 April 2016 pursuant to Wei-Bu-Yi-Zi No. 1051662154)

4.名詞定義

4. Definitions

4.1 資料與安全性監測計畫(Data & Safety Monitoring Plan,簡稱 DSMP)

此計畫內容為試驗計畫主持人用以監督管理受試者之安全,包括:不良事件應如何被紀錄及通報;計畫監測的廣度及頻率應該根據可預期之試驗風險、複雜度及研究計畫的大小訂定。IRB 審查時根據計畫需要,得要求建置 DSMP。

4.1 Data and Safety Monitoring Plan (DSMP)

A DSMP describes how the principal investigator plans to oversee the trial subject's safety, including how adverse events will be characterized and reported. The intensity and frequency of monitoring should be commensurate with the potential risks, the complexity and size of the protocol. The IRB has the authority to request a DSMP, when necessary.

4.2 資料與安全性監測委員會(Data & Safety Monitoring Board,簡稱 DSMB)

一群獨立的專家組成之委員會,評估常規審查臨床試驗進行所累積之試驗數據。此委員會獨立公正的評估與監測計畫之執行與結果,提供主持人及委託廠商對進行中計畫做最適當的決策與處置,以維護後續受試者之安全及試驗設計與數據之正確性。

4.2 Data and Safety Monitoring Board (DSMB)

A DSMB is a committee made up of an independent group of experts that reviews accumulated data from clinical trials at regular intervals. The DSMB evaluates and monitors research conduct and efficacy impartially, and advises the principal investigator and the sponsor on the continuing safety of trial subjects and the continuing precision of protocol design and data.

5.作業內容

5. Procedure

5.1 資料與安全性監測計畫管理流程圖

5.1 Flow Chart of Data and Safety Monitoring Plan

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
頒布DSMP原則 Publish DSMP Guidelines ↓ 隨計畫提出DSMP Investigator-initiated DSMP with protocol submission ↓ 隨計畫審查 Review of DSMP with the protocol ↓ 紀錄保存 Records retention	第一/二人體研究倫理審查委員會 The First/Second IRB Committees 計畫主持人 Principal Investigator 委員 IRB Members 承辦人員 Staff Members	DSMP 原則 DSMP Guidelines 計畫書 Protocol 計畫書/監測報告 Protocol /Monitoring Report

5.2 頒布 DSMP 原則

5.2 Guidelines for Developing a DSMP

5.2.1 本委員會提供 DSMP 原則如下（可多選）：

5.2.1 The following guidelines have been provided by the IRB (multiple conditions may be applicable):

5.2.1.1 依風險程度定期繳交追蹤審查報告，摘要試驗進度（如：收案三人或滿三個月）。

5.2.1.1 A Continuing Review of protocol progress shall be submitted at intervals appropriate to the degree of risk (e.g., after three trial subjects are enrolled or when the trial has been conducted for three months).

5.2.1.2 即時繳交嚴重不良反應報告/國外安全性通報，並注意本院受試者狀況。

5.2.1.2 Serious adverse event reports/international patient safety alerts shall be submitted in a prompt manner. Special attention shall be given to the well-being of trials subjects.

5.2.1.3 提出額外之受試者保護措施，如：易受傷害族群。

5.2.1.3 Additional protection shall be provided for trial subjects, e.g., vulnerable populations.

5.2.1.4 增加監測頻率，如：進行實地訪查或定期內部監測。

5.2.1.4 Monitoring frequency shall be increased, e.g., conducting an on-site inspection or internal monitoring at periodic intervals.

5.2.1.5 增加與其它參加試驗單位的聯絡頻次。

5.2.1.5 Contact frequency with all units involved in the trial shall be increased.

5.2.1.6 成立資料與安全性監測委員會。

5.2.1.6 A Data and Safety Monitoring Board (DSMB) shall be established.

5.2.1.7 高風險試驗訂立試驗執行停損點。

5.2.1.7 Trial stopping rules shall be established for protocols involved trials with significant risks.

5.2.1.8 其它。

5.2.1.8 Others.

5.3 隨計畫提出 DSMP

5.3 Investigator-initiated DSMP

5.3.1 試驗主持人於送審計畫時，應先自行評估研究風險等級。高於最小風險之研究，試驗主持人應主動將 DSMP 增列於其計畫書內。審查委員如提出應訂定 DSMP 時，主持人應予修正。

5.3.1 The principal investigator is responsible for assessing risk level of the research protocol before submitting a protocol. The principal investigator is required to include a DSMP in the protocol if the research presents more than minimal risk to the subjects. Should the reviewers determine that a DSMP is required, the principal investigator shall comply.

5.3.2 本委員會針對下列條件，得要求計畫書內需具備 DSMP：

5.3.2 The IRB may request a DSMP in a protocol in the following circumstances:

5.3.2.1「人體試驗管理辦法」第二條規範之「新藥品、新醫療器材於辦理查驗登記前，或醫療機構將新醫療技術，列入常規醫療處置項目前」之人體試驗。(如：本國未上市新藥、新醫療器材之查驗登記與學術研究案，需提報衛生福利部審查之新醫療技術案)，且風險較高者。

5.3.2.1 Research involving human trials and presenting greater than minimal risk to subjects shall include a DSMP. According to Article 2 of the Regulations on Human Trials: “A human trial research shall be conducted prior to the registration of a new drug or medical device or before a medical care institution lists a new medical technology as a regular medical

disposition item" (e.g., domestically developed new drugs that are not approved for sale, registration of and research projects on new medical devices, and new medical technologies that require approval from Ministry of Health and Welfare).

5.3.2.2 不論有無委託廠商，但經本委員會會議討論後，認定風險較高之案件【如：顯著超過最小風險及高風險案件】。

5.3.2.2 The risk level of a research protocol is determined to be high by the IRB regardless of the presence or absence of a sponsor (e.g. protocols that pose more than a minor increase over minimal risk and those that pose significant risk).

5.3.2.3 研究對象為特殊易受傷害群體受試者，不論有無委託廠商，經本委員會會議個案討論後決議之案件。

5.3.2.3 Trials in an IRB-approved protocol that include subjects considered vulnerable research population, regardless of the presence or absence of a sponsor.

5.3.2.4 計畫主持人自行評估「風險利益」後，主動提出 DSMP 之案件。

5.3.2.4 The principal investigator proposes a DSMP after assessing the "risk-benefit" ratio of the research protocol.

5.3.2.5 其它特殊情形。

5.3.2.5 Other special circumstances.

5.3.3 承辦人員於收到送審資料時應初步確認送審資料之完整性，否則得要求試驗主持人補件後再送審。

5.3.3 At the time protocol materials are received, all documents shall be examined for compliance with submission requirements. The IRB staff members perform a preliminary review of the protocol. Incomplete submissions will not be accepted for review until the principal investigator has provided all necessary materials

as determined by the IRB staff.

5.4 隨計畫審查

5.4 Review of DSMP with the protocol

5.4.1 承辦人員必須依初審案件送審流程，儘速分派案件予各主審委員，並追蹤各委員之審查時間，於委員會議召開前回收審查意見。

5.4.1 When processing protocols for primary review, the IRB staff members shall distribute the protocols to designated reviewers promptly in compliance with the review process. The IRB staff is also responsible for coordinating timelines among reviewers and collecting individual reviews prior to the scheduled IRB board meeting.

5.4.2 委員審查案件時評估風險程度，並評估 DSMP 之適切性

5.4.2 The IRB shall determine the level of risk for proposed research protocols and evaluate the appropriateness of the DSMP.

5.4.2.1 本委員會提供 DSMP 原則，建議主持人依據時間順序【如：試驗前篩選與收納期、試驗進行期、試驗後追蹤期】，說明計畫中預定採取保護受試者的措施與動作內容。

5.4.2.1 The principal investigator is advised to address, in chronological order, proposed safety measures and action plans for trial subjects in the research protocol (e.g., the three periods of a trial: before - screening and enrollment; during - treatment; and after - follow-up).

5.4.2.2 委員審查 DSMP 應綜合評估研究計畫之風險程度。因此 DSMP 應參考下列項目：

5.4.2.2 When reviewing a DSMP, the IRB shall assess the overall degree of risk involved in the protocol. A DSMP shall therefore include the following elements:

a.應監測試驗的執行與受試者的保護措施。

a. Monitoring trial conduct and safety measures for trial subjects.

b.應試驗發生的不良事件/嚴重不良事件皆會被正確的通報並統計。

b. Accurately reporting and documenting any adverse events/serious adverse events.

c.應向相關單位通報任何導致臨床試驗暫停/終止的行為。

c. Reporting any actions that may cause the clinical trial to be suspended/terminated to the authorities concerned.

d.應按照試驗計畫書執行試驗，蒐集之數據確實可信。

d. Conducting trials in accordance with the protocol and assuring the validity and integrity of collected data.

e.若為多中心試驗，應確保各中心間的聯繫通暢，以保障受試者的安全。

e. Conducting regular communications with all participating centers to ensure the safety of trial subjects should the protocol include multicenter trials.

f.其它保護受試者與計畫內容措施，包括：
何人來執行監測?監測方式與內容?向誰報告?主持人自己監測時，如何迴避利益衝突?如何偵測不良事件?非預期不良反應事件通報？嚴重不良事件通報？期中數據分析，暫時性分析?多中心試驗橫向聯繫?確保品質?風險管理與停損點?暫停/終止執行之條件?後續照護計畫?如已成立 DSMB，請詳述組成結構、功能、及運作方式?其它任何保護受試者權益行動...等。

f. Providing other means of protection for the trial subjects and the protocol, for instance:

Who will be responsible for monitoring? How will

monitoring be performed and what are the details? Who will monitoring be responded to? How will the principal investigator avoid conflict of interest of the DSMB if he/she is the one performing monitoring? How will adverse events be identified? How will unanticipated adverse events be reported? How will serious adverse events be reported? Will midterm data analysis or temporary analysis be performed? How will communication exchange occur in a multi-center research? How will quality be assured? What are the details about risk management and trial stopping rules? What are the rules for suspending/terminating a trial? Will there be a care program? If a DSMB has been established, please describe its organizational structure, function and operation in detail. What actions will be taken to protect the rights of trial subjects?

5.4.3 本委員會視個案情形，可以要求試驗主持人/委託廠商組成 DSMB。主審委員審查時，必須注意 DSMB 成員的適當性及功能性。考慮因素包括領域專長、是否有利益衝突及成員人數等。

5.4.3 A DSMB may be formed by the principal investigator/sponsor of the trial if the IRB deems it necessary. Members of the DSMB are to be carefully selected based on their suitability and function, including relevant expertise, absence of conflict of interest, and proposed number of members.

5.4.4 DSMB 之職責在於獨立、公正之監測計畫之執行，提供主持人及委託廠商對進行中計畫做最適當的決策與處置。同時，本委員會得要求計畫主持人適時繳交「監測報告」，內容包括不良事件分析、監測頻率、主要次要療效指標，或是提出任何修正計畫內容之依據或建議。

5.4.4 The DSMB has impartial, independent decision-making responsibilities to monitor research conduct and make

recommendations for modifications or amendments concerning ongoing protocols to the principal investigator and the sponsor. The DSMB may request the principal investigator to submit, at appropriate intervals, a "Monitoring Report" in which analysis of adverse events, monitor frequency, and analyses of primary and secondary efficacy endpoints are included.

5 .4.5 本委員會有權於追蹤審查或試驗安全有疑慮時，要求試驗主持人說明或增加/修改已核准之 DSMP 內容，以確保受試者之安全。

5.4.5 The IRB has the authority to require the principal investigator to clarify or add to/revise an IRB-approved DSMP when concerns about continuing review or trial safety are raised.

5.4.6 委員會議決定是否修改 DSMP

5.4.6 The IRB determines whether the DSMP requires modification/amendment.

5.4.6.1 初審委員應說明審查 DSMP 之意見，並於委員會議中討論。

5.4.6.1 The primary reviewers are expected to discuss and provide comments about the approval of a DSMP review in a board meeting.

5.4.6.2 大會決議初審案件是否通過時，應一併考量 DSMP 之適切性。

5.4.6.2 The IRB is responsible for evaluating the appropriateness of the DSMP when approving the primary reviews of protocols in a board meeting.

5.4.7 持續審查追蹤 DSMP 執行成效

5.4.7 Continuous review and monitoring of the effectiveness of the DSMP is advised.

5.4.7.1 試驗計畫主持人繳交期中及結案報告時，應提及 DSMP 相關事件及處置。

5.4.7.1 The principal investigator is responsible for addressing DSMP-related incidents and procedures taken in the midterm and final reports of the research.

5.4.7.2 若主持人不按照計畫（包括 DSMP）進行時，大會有權要求進行實地訪查或暫停/終止試驗之進行，以確保受試者之安全。

5.4.7.2 The IRB has the authority to request an on-site inspection or suspend/terminate approval of a trial that is not being conducted in accordance with the protocol (including a DSMP) by the principal investigator to assure the safety of trial subjects.

5.5 紀錄保存

5.5 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	監測報告 Monitoring Report	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed

6.附件

6. Appendix

無。

None.