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A	9	新訂。 Newly composed.	20140519					
В	9	由人體試驗委員會標準作業程序 5.4 版轉換成此版本。 20150119 This version was converted from "Version 5.4 of the SOP of the Human Research Committee."						
С	8	 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」,並補充其英文名及簡稱。 The original "Human Research Committee" was renamed "The First/Second IRB Committees," and its English name and acronym were added. 文句修訂。 Minor changes in the wording. 新增 29. IRB 標準化文件內文之「/」符號意義。 						
		 Item 29 was added regarding the meaning of slash (/) in a standardized document. 						
D	20	 修改 2.2.4 IRB 委員具備知識:刪除法律。 Item 2.2.4 was revised regarding the background knowledge of IRB members: "Law" was deleted. 修改 4.2 人體試驗相關訓練改為人體研究,並舉例。 Item 4.2 was revised: "Training related to clinical trials" was replaced by "human research," and examples were added. 修改 4.2 及 14.註:2 人體試驗管理辦法版次。 The Version of "Regulations on Human Trials" was updated in item 4.2 and the note to item 14. 						
		 4. 修改 9.2 初步審查期限:原7個日曆天。 4. Item 9.2 was revised regarding the time limit of initial review: The original was "7 calendar days." 						

		臺中榮民總醫院 Taichung Veterans General Hospital		
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E	19	 修改 10.2.4 表單名稱。 The wording of the title of item 10.2.4 was revised. 修改第 12 項之子編號。 	20190527	
		 Revised the sub-numbers of item 12. 修改原 12.4 為"經中央主管機關、廠商或主持人來文 通知停止執行之計畫。" 		
		 Revised item 12.4 to be "On the order of the central authority, manufacturer or principal investigator, stop the execution of study." 		臺中榮民總醫
		 4. 原 12.5 內容移至名詞解釋之敘述。 4. Contents of the original item 12.5 be moved to glossary. 		023.08. 參考文作
		5. 刪除原 12.6 內容。 5. Delete original contents of item 12.6. 6. 修改 16: 会議書边授医 名數边 為 臣則。		
		 6. 修改 16: 會議表決採匿名多數決為原則。 6. Revised item 16 to "voting in the meeting adopts the principle of majority in anonymity". 		
		 7. 更新藥事法第7條及第13條之定義。 7. Updated the definition of Article 7 and Article 13 of the Pharmaceutical Affairs Act. 		
F	19	1. 文字校訂。	20210528	
		1. Typos were fixed.		
		2. 修改 3.1: IRB 得接受特定院外機構提出的人體試驗		
		計畫案,並依IRB相關規定進行審查。		
		2. Revised item 3.1 to "The IRB may accept protocol		
		submissions of clinical trials by specific institutions		
		outside TCVGH and conduct review according to		
		IRB regulations."		
		3. 刪除 3.2.4 內容。 3. Deleted item 3.2.4.		
		4. 修改8.「異常問題」為「不遵從事件」。		
		4. Revised Item 8 "Abnormal problem" to "Non-compliance."		

		臺 中 榮 民 總 醫 院 Taichung Veterans General Hospital
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	No. Page	Summary of Revisions of the Document Date of Implementation
F	19	 5. 修改 10.1:當計畫結束時,計畫主持人需繳交結案 20210528 報告給人體研究倫理審查委員會。 5. Revised item 10.1 to "When a study is completed, the PI should submit a closing report to the IRB." 6. 更新法規名稱及公告日期。 6. Revised the name of the regulation and the announcement date. 7. 18.2.「人體試驗委員會」更名為「人體研究倫理審 查委員會」。 7. Item 18.2: "Human Research Committee" was renamed "IRB." 8. 修改 18.3:承辦人員會定期提醒主持人繳交此報告。 8. Revised item 18.3 to "The IRB staff member will periodically remind the PI to submit the above-mentioned report." 1. 修改 9.2 審查期限:原6個日曆天改為6個工作天。 20211209
G	19	1. 修改 9.2 番查期限 · 原 6 個日曆天改為 6 個工作天。 1. Revised item 9.2 Review time limit: Replaced "six calendar days" with "six work days." 本欄空白 · 接續下頁 · Blank. Continued on next page.

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1 12 Increased the qualification requirements for the 1202B.							
Principal Investigator of medical device clinical							
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核章紀錄之正本儲放於SOP管理中心							

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	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
》 挂夕 合立	 	

※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.

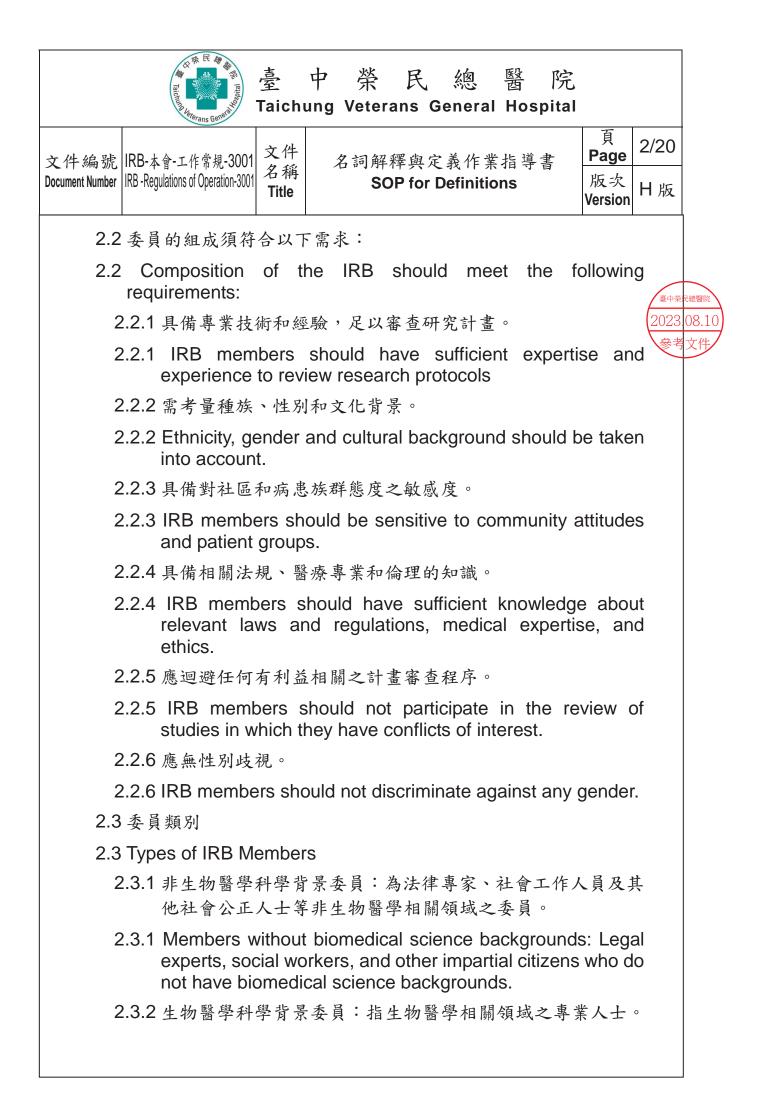


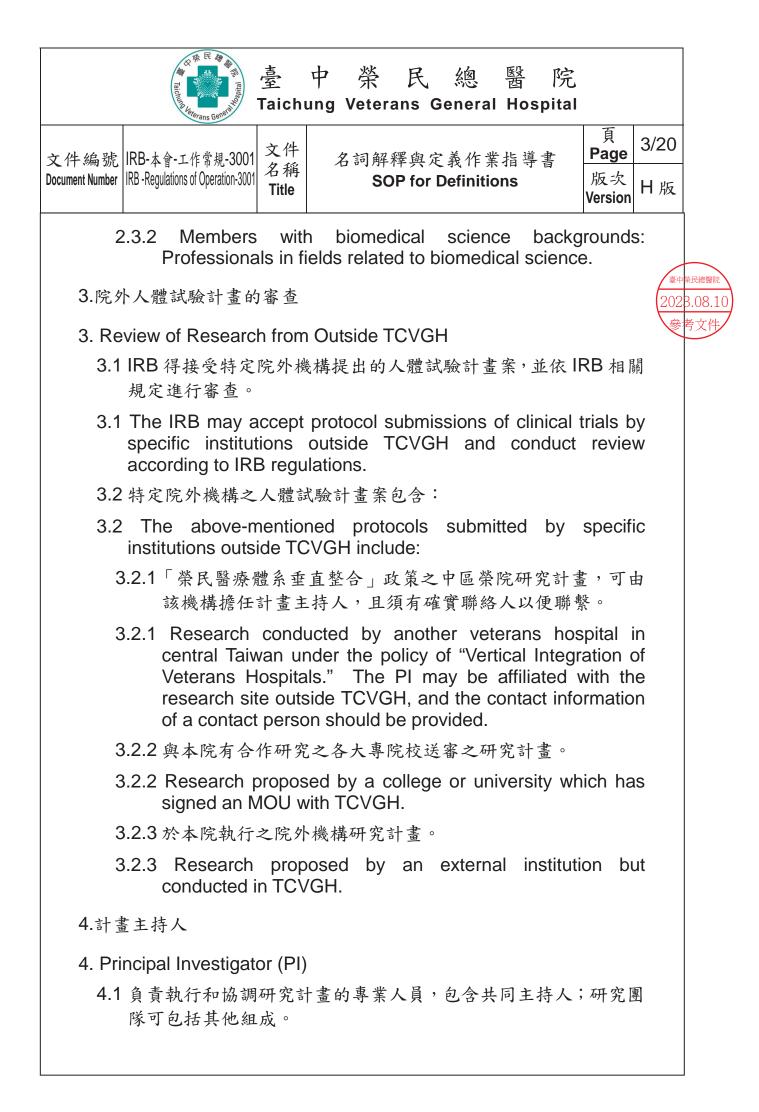
1.人體研究倫理審查委員會(Institutional Review Board,簡稱: IRB) 之宗旨

- 1. The Purpose of the Institutional Review Board (IRB)
 - 1.1 IRB 設立之宗旨是審查和監測以人為受試對象的醫學和社會科 學研究,確保受試者的權益和福祉。依據本國、國際現行法規和 社會倫理價值, IRB 有權同意、要求修正和不同意研究的進行。

榮民總醫

- 1.1 The purpose of the IRB is to review and monitor medical and social science studies involving human subjects to ensure the protection of the subjects' rights and welfare. In compliance with local and international regulations and social ethical values, the IRB has the authority to approve, request amendment of, or disapprove the implementation of a study.
- 1.2 IRB 依法成立,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(依人體研究法第7條規定辦理)。
- 1.2 The establishment of the IRB should comply with law and regulations. The IRB should consist of five or more members, including legal experts and other impartial citizens. At least two-fifths of the IRB members should not be affiliated with TCVGH. The IRB should include both men and women, and the number of the representatives of each gender shall not be less than 1/3 of the total members. (in compliance with Article 7 of Human Subjects Research Act).
- 2.IRB 委員
- 2. IRB Membership
 - 2.1 符合 IRB 之遴聘資格和專業資歷等必要條件(詳見 IRB-本會-人員管理-2001 人體研究倫理審查委員會組織章程)。
 - 2.1 IRB members should have the required qualifications and expertise (as defined in the document "IRB-Personnel Management-2001-The Organizational Charter of the First/Second IRB Committees").





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4.1 The PI is responsible for implementing the research and coordinating among research personnel including co-investigator and other members of the research team.								
		關訓練(如:研究作 內達6小時以上。	命理、法律、	·臨床言	式			
 4.2 The PI should receive at least six hours of training related to human research (e.g. research ethics, law, clinical trial, GCP) within the past three years. 【依「人體試驗管理辦法」(2016 年 04 月 14 日衛生福利部衛部 								
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All Productions 名稱 Title SOP for Definitions 版次 Version H版 整材臨床試驗及醫學倫理各九小時之相關課程。 2. Having received 30 hours of clinical trials related training within the past 6 years, including at least 9 hours of related training courses each for clinical trial of medical devices, and medical ethics. 三、試驗用醫療器材必要操作能力,經取得證明文件。 3. Possessing necessary ability to operate the investigational medical device and related certificates. 4.3 本院護理人員擔任計畫主持人,應具下列資格之一: 4.3 A TCVGH-employed nurse should meet one of the following requirements to be qualified to serve as PI: 4.3.1 副護理長(含)以上職務。 4.3.1 Holding the rank of deputy chief nurse or higher. 4.3.2 具碩士學歷(含)以上。 4.3.2 Holding a master's or higher degree. 4.3.3 Holding an N3 certificate and a bachelor's or higher degree. 4.2.4 預依規定接受人體試驗相關訓練,3 年內達6 小時以上。 4.2.4 Having received at least 6 hours of clinical trial training within the last three years. 5.協調人 5.Coordinator 在人體試驗研究地點負責管理該計畫案之人員,計畫主持人可同時擔	寸化绝瑞	IRB-太命-工佐受坦-3001	文件	夕詞解釋的	完善作类	长道士		6/20	
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The coordinator is responsible for protocol management on the research site. The PI may also serve as coordinator. 6.進行中計畫之檔案	4.3 4.3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	2. Having rece within the past training courses medical ethics. 三、試驗用醫療 3. Possessing medical device 本院護理人員擔 A TCVGH-emp requirements to 4.3.1 副護理長(4.3.1 Holding the 4.3.2 具碩士學歷 4.3.3 Holding and 4.2.3 具 N3 證書 4.3.3 Holding and 4.2.4 須依規定接 4.2.4 須依規定接 4.2.4 須依規定接 4.2.4 月aving reconstruct 潮調人。 coordinator 人體試驗研究地黑 6. The PI may als	ived 30 h 6 years, 6 years, s each for S each for	ours of clir including a clinical tria 操作能力, ability to o d certificate 持人,應具 se should ed to serve 截務。 eputy chief 上。 higher deg (含)以上。 tificate and 彙相關訓練 least 6 hou ears.	<u>hical trial</u> <u>t least 9</u> <u>al of mec</u> <u>經取得證</u> <u>perate t</u> <u>医</u> 下列資格 meet one as PI: nurse or gree. ^要 是 者 。 d a back , 3 年內 urs of cli	s <u>relate</u> hours <u>dical dev</u> <u>dical dev</u> <u>明文件。</u> <u>he inves</u> 之一: e of the higher. helor's 達 6 小時 nical tria 畫主持人	of relate vices, an stigationa followin or highe u上。 al trainin	ed id al ig er ig	中桌民總醫院 23.08.1(拿考文件

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6. Do	cuments of Rese	earch	in Progress				

經 IRB 核准且正在執行之計畫的相關文件,包含送審文件、計畫書、 審查意見、核准公函、紀錄、報告和往返信件等。

Documents related to IRB-approved protocols of research in progress include submission documents, protocols, review comments, official letters of approval, records, reports, and other correspondence.

7.行政文件

7. Administrative Documents

指 IRB 會議紀錄、投票紀錄、公函和標準作業程序等。如標準作業 程序所記載之歷史性檔案與主檔、標準作業程序分送與執行和檔案維 護等文件。

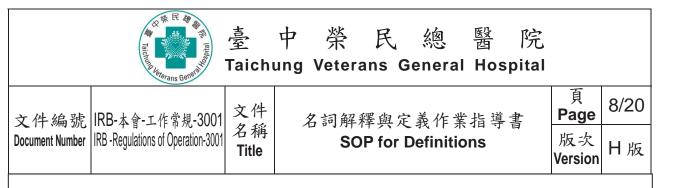
Administrative documents include IRB meeting minutes, voting records, official letters, and standard operating procedures (SOPs). Documents recorded in the SOPs are also included, such as outdated files and original files, records related to the distribution and implementation of SOPs, and documents related to file management.

8.不遵從事件【偏離(Deviation)、背離(Violation)】

8. Non-compliance [Protocol Deviation/Violation]

指計畫主持人/機構未依照審查通過之計畫書執行計畫、未遵循國內/ 國際人體試驗相關法規或未依照 IRB 要求提供資訊之行為,及受試 者未依據所簽署受試者同意書之研究方法內容配合進行研究之行為 (詳見 IRB-本會-工作常規-2016 試驗偏離/背離的處理管理程序書)。 A protocol deviation/violation refers to (1) a departure from the approved protocol's procedures; (2) a failure to comply with relevant national/international law or regulations regarding human research ethics; (3) an act in which the information required by the IRB is not provided; or (4) an act in which the subjects' participation in the study is not in accordance with the study design described in the signed ICF (for details, refer to the document titled "IRB--Regulations of Operation-2016-SOP for Protocol Deviation/ Violation").





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9.簡易審查

9. Expedited Review

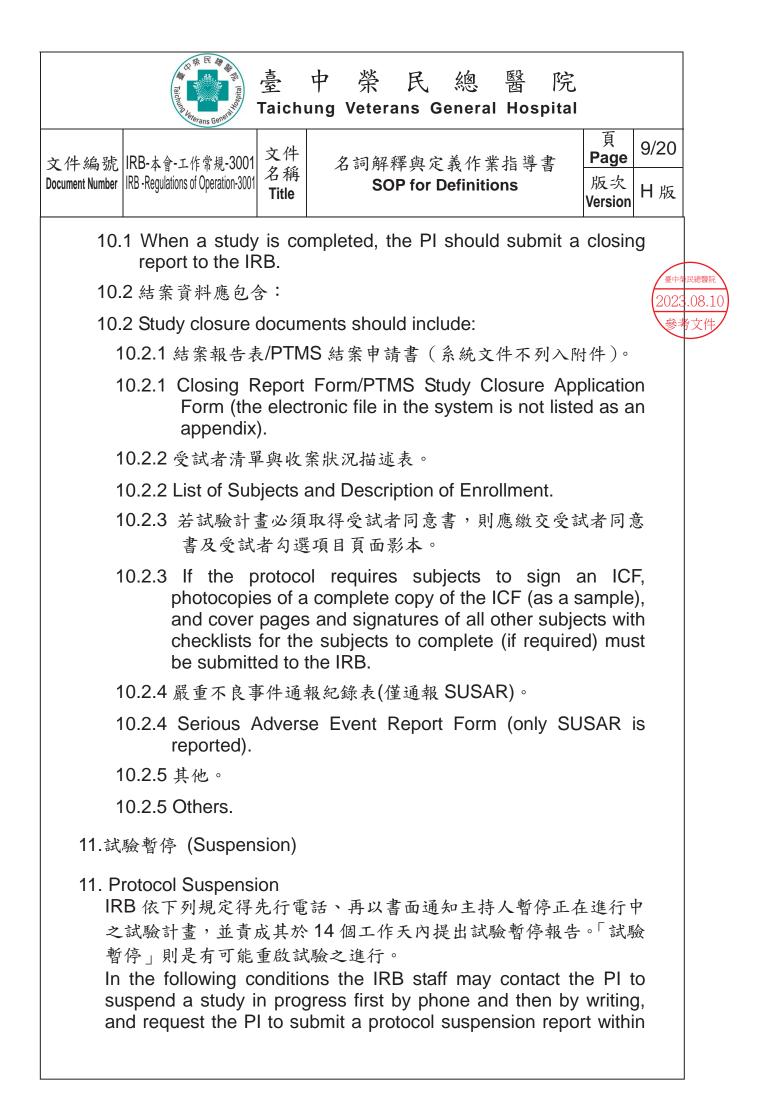
9.1 由計畫主持人填寫「臨床研究簡易審查範圍核對表」。

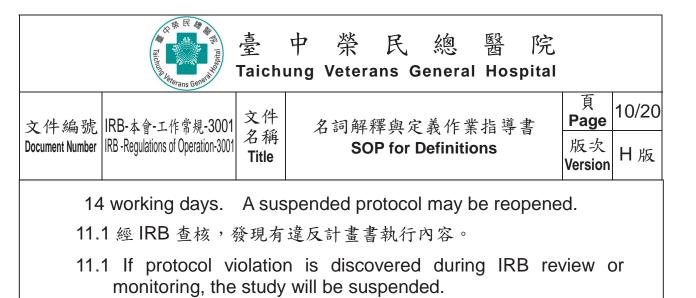
- 9.1 The PI should fill in the Expedited Review Checklist.
- 9.2 依據「臨床研究簡易審查範圍核對表」所列條件評估是否適用簡 易檢查,經執行秘書、(副)主任委員判定符合簡易審查要件, 指派二位審查委員在6個工作天內完成初步審查。若其中任何一 位審查委員認為不適用簡易審查,應改為一般審查,即按一般審 查程序進行。
- 9.2 The Executive Secretary and the (Vice) Chair should review the Expedited Review Checklist filled by the PI to determine if the protocol is eligible for expedited review. If it is, two reviewers should be assigned to complete primary review of the protocol within 6 work days. If one of the reviewers determines that the protocol is not eligible for expedited review, the protocol should be sent to the full board for review following the full board review procedure.
- 9.3 整個簡易審查流程當中,若發現不符合簡易審查之適用範圍,應 立即提出並陳述理由,由主任委員裁決得改為一般審查。若對上 項理由有疑慮者,應以採一般審查為原則。
- 9.3 During the process of expedited review, if the reviewer discovers that the protocol is not eligible for expedited review, the reviewer should state reasons and report to the IRB office for the IRB Chair to determine if the protocol should be sent to the full board for review. If there are doubts regarding the above-mentioned reasons stated by the reviewer, the protocol is principally sent to the full board for review.

10.結案報告

10. Closing Report

10.1 當計畫結束時,計畫主持人需繳交結案報告給人體研究倫理審 查委員會。





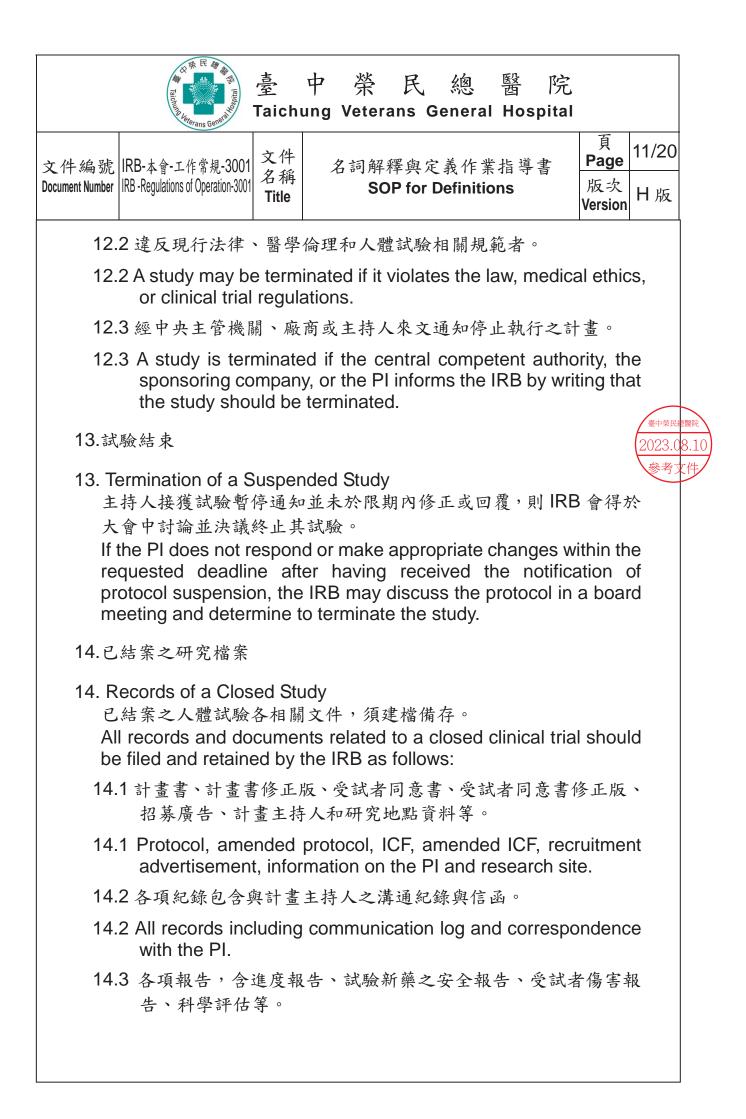
- 11.2 經中央主管機關、廠商或主持人來文通知暫停執行之計畫。
- 11.2 A study is suspended if the central competent authority, the sponsoring company, or the PI informs the IRB by writing that the study should be suspended.
- 11.3 違反現行法律、醫學倫理和人體試驗相關規範者。
- 11.3 A study is suspended if it violates the law, medical ethics, or clinical trial regulations.
- 12.試驗終止(Termination)
- 12. Protocol Termination

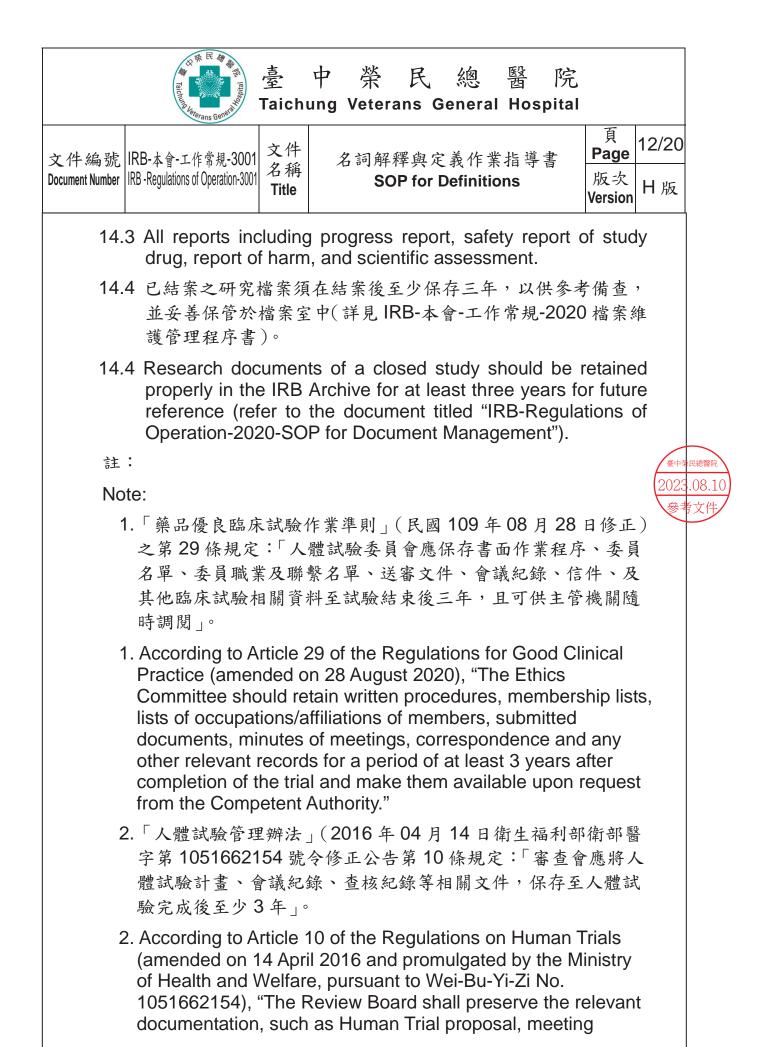
「試驗終止」意指尚未依計畫書執行完成、或是發現計畫的安全性 或效益有疑慮、計畫的風險增加時,本會、計畫主持人或廠商皆可 決定中途停止收案,且不會再重啟試驗。IRB依下列規定得先行以 電話、再採書面通知主持人停止正在進行中之試驗計畫,並責成其 於14個工作天內提出試驗終止報告。

Protocol termination refers to the permanent cessation of all research activities requested by the IRB, the PI, or the sponsoring company when there is a concern about the safety or effectiveness of a trial or when there is an increased risk presented to the subjects. A terminated protocol may not be reopened. The IRB staff may contact the PI to terminate a study in progress first by phone and then by writing, and request the PI to submit a protocol termination report within 14 working days.

- 12.1 經 IRB 查核發現有違反計畫書執行內容,且情節重大足以影響 受試者安全。
- 12.1 If serious protocol violation is discovered during IRB review or monitoring and the violation may affect the safety of the subjects, the study will be terminated.







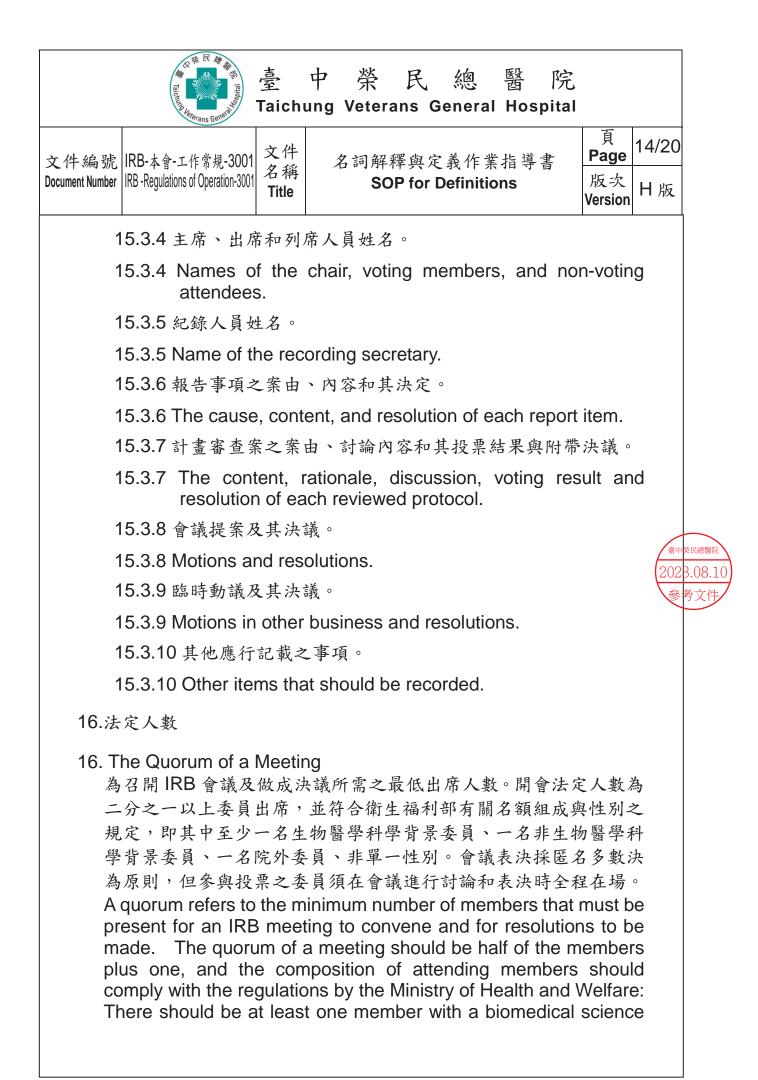


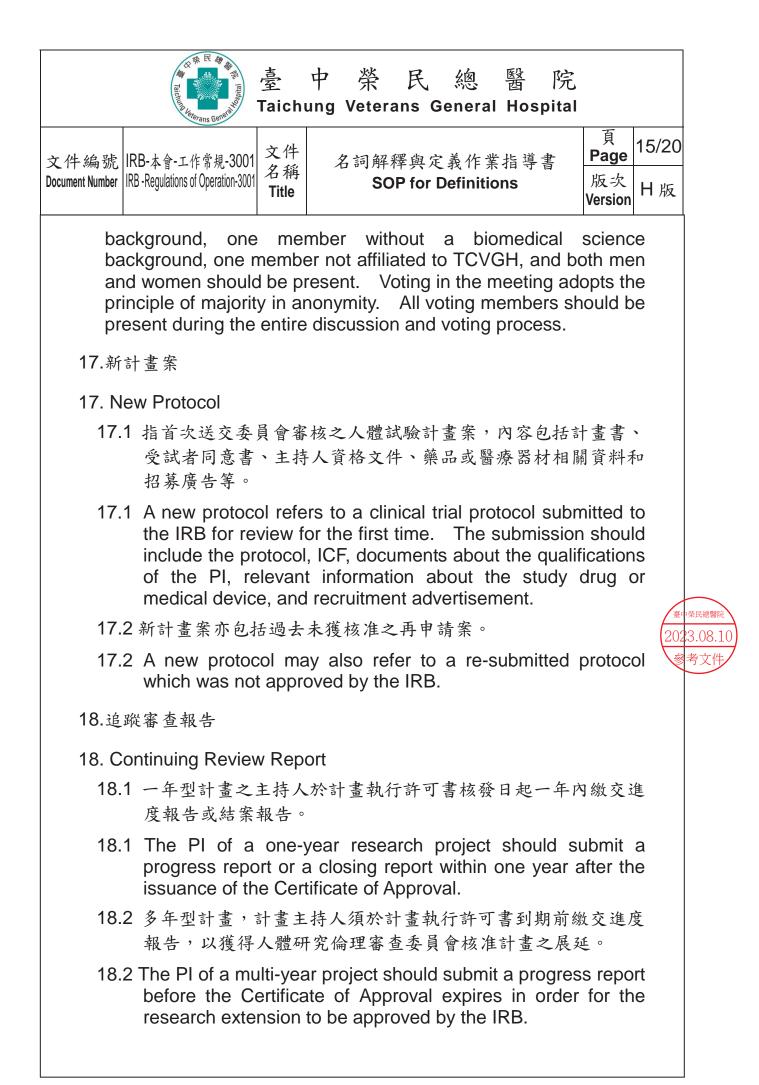
- 15. Meeting Minutes
 - 15.1 係指記載達法定出席人數之 IRB 審查會議之正式紀錄。
 - 15.1 Meeting minutes refer to the official minutes of an IRB review meeting where a quorum was present.
 - 15.2 記載會議議程所列的事件、活動和決議。會議記錄完整地標示 出每件計畫或議案,並紀錄各項表決的結果。委員會對送交審 查的每份計畫分別表決,表決紀錄係採不記名方式,僅註明核 准、修正後核准、修正後複審、不核准與棄權的票數,和修正 意見。
 - 15.2 Events, activities, and resolutions related to the agenda items of a meeting should be recorded in the minutes. The minutes should record the voting result for each protocol and motion on the agenda. Each protocol on the agenda should be voted on separately. The voting results should be recorded anonymously. Only the number of votes for each option (approval, approval after revision, further review after revision, disapproval, and abstention) and comments for revision should be recorded.

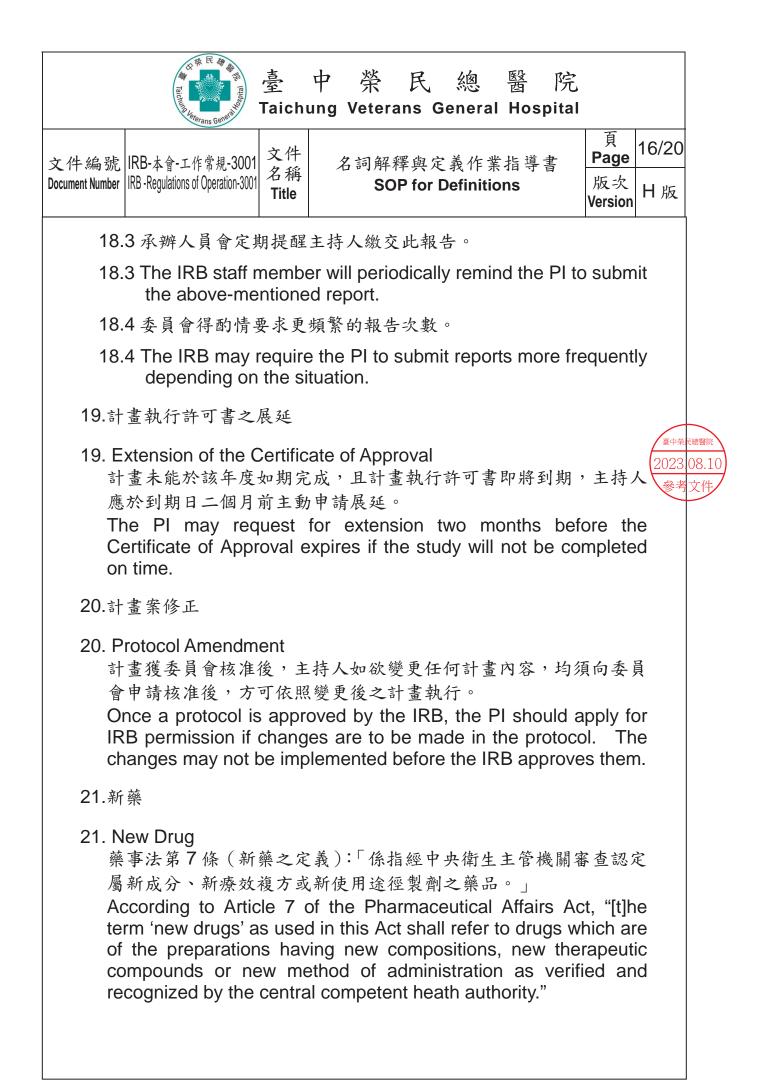
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- 15.3 會議記錄記載:
- 15.3 The minutes should include the following items:
 - 15.3.1 會議期數。
 - 15.3.1 Meeting session.
 - 15.3.2 會議時間。
 - 15.3.2 Meeting time.
 - 15.3.3 會議地點。
 - 15.3.3 Meeting location.







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文件编號 IRB-本會	·-工作常規-3001 文件	名詞解釋與定義作業指導書	頁 Page 17/20
文件編號 IRB-本會 Document Number IRB-Regula	ions of Operation-3001 名稱 Title	SOP for Definitions	版次 Version H 版

22.新醫療器材

22. New Medical Device

- 22.1 涉及新醫療器材之臨床試驗,其目的乃測試此器材之安全性或 適用性。
- 22.1 The purpose of a new medical device clinical trial is to test the safety or functionality of the device.
- 22.2 藥事法第 13 條:「本法所稱醫療器材,係用於診斷、治療、減輕、直接預防人類疾病、調節生育或足以影響人類身體結構及機能...之儀器、器械、用具、物質、軟體、體外試劑及相關物品」。
- 22.2 According to Article 13 of the Pharmaceutical Affairs Act, "[t]he term 'medical device', as used in this Act, shall refer to any instruments, machines, apparatus, materials, software, reagent for in vitro use, and other similar or related articles, which is used in diagnosing, curing, alleviating, or directly preventing human diseases, regulating fertility, or which may affect the body structure or functions of human beings."

23.低風險性器材

23. Low-Risk Medical Device

低風險性器材係指比臨床風險低之試驗性醫療器材。

A low-risk medical device refers to an investigational medical device that poses less risk than a similar device used in clinical practice.

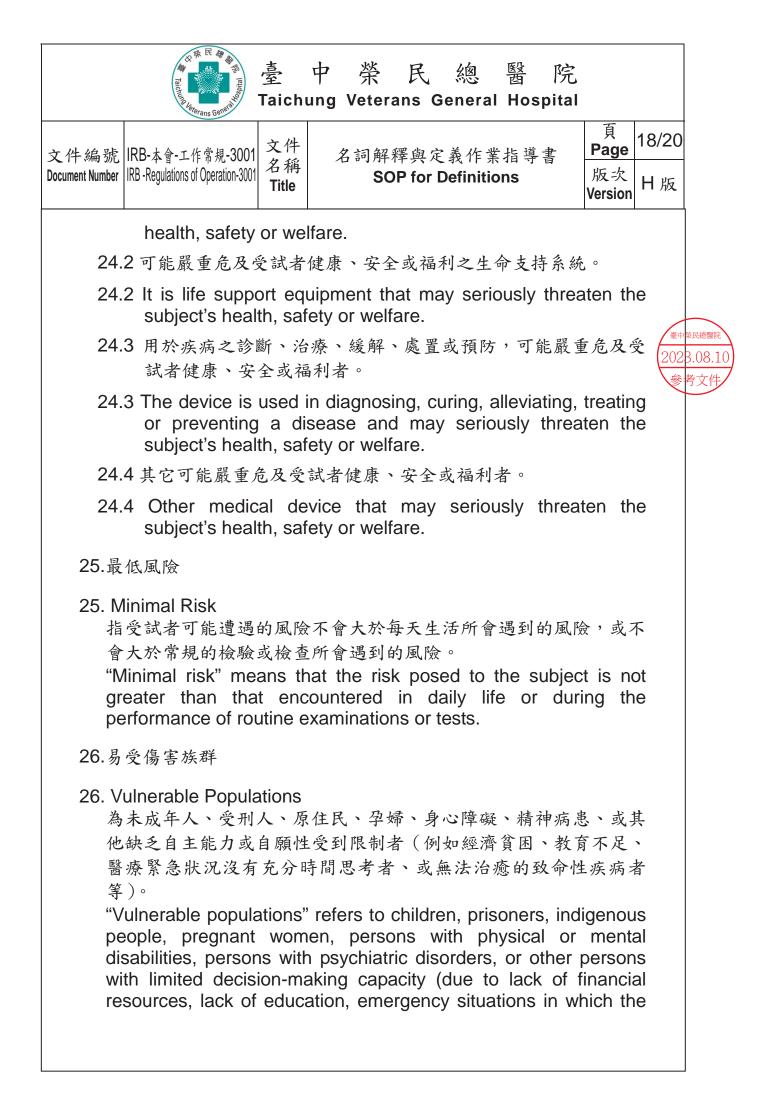
24.高風險性器材

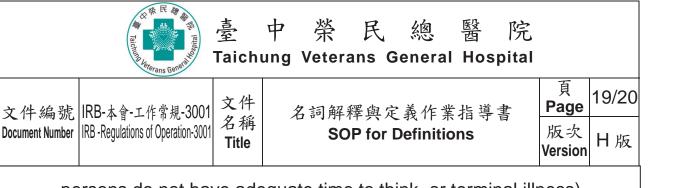
24. High-Risk Medical Device

高風險性器材係指具有下列情況之試驗性醫療器材: A high-risk medical device refers to an investigational medical device that fits one of the following descriptions:

24.1 可能嚴重危及受試者健康、安全或福利之置入物。

24.1 It is an implant that may seriously threaten the subject's





persons do not have adequate time to think, or terminal illness).

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27.名詞新增和變更

- 27. Addition and Changes of Terms
 - 27.1 IRB 委員得隨時提出新增任何名詞,或對本標準化文件之任何 定義提出修正建議。
 - 27.1 IRB members may propose to add new terms or propose changes of any definitions in this standardized document.
 - 27.2 書寫新增或變更提案。
 - 27.2 The addition or change of a term is proposed by writing.
 - 27.3 將新增或變更提案送交 IRB 承辨人員。
 - 27.3 The proposal of addition or change should be submitted to the IRB staff.
 - 27.4 由標準化文件小組開會討論後,提大會決議並核准。
 - 27.4 A meeting is convened by the Document Revision and Standardization Group to discuss the proposal. The resolution from the meeting should be submitted to the IRB board meeting for approval.

28.標準化文件內容增修

- 28. Revision of Standardized Documents
 - 28.1 IRB 委員得隨時提出新增或修正標準化文件之建議。
 - 28.1 IRB members may propose addition or revision of a standardized document.
 - 28.2 建議案在標準化文件小組會議中進行討論。
 - 28.2 A meeting is convened by the Document Revision and Standardization Group to discuss the proposal.
 - 28.3 標準化文件小組提大會中作成決議並核准。
 - 28.3 The Document Revision and Standardization Group makes a resolution and submits it to the IRB board meeting for

