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-3001 IRB-Regulations of Operation-3001	文件名稱 Title	名詞解釋與定義作業指導書 SOP for Definitions
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：人體研究倫理審查委員會 ■Other (Please specify): The IRB Committees		

版次 Version	頁數 No. Page	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
A	9	新訂。 Newly composed.	20140519
B	9	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	8	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」，並補充其英文名及簡稱。 1. The original “Human Research Committee” was renamed “The First/Second IRB Committees,” and its English name and acronym were added. 2. 文句修訂。 2. Minor changes in the wording. 3. 新增 29. IRB 標準化文件內文之「/」符號意義。 3. Item 29 was added regarding the meaning of slash (/) in a standardized document.	20160318
D	20	1. 修改 2.2.4 IRB 委員具備知識：刪除法律。 1. Item 2.2.4 was revised regarding the background knowledge of IRB members: “Law” was deleted. 2. 修改 4.2 人體試驗相關訓練改為人體研究，並舉例。 2. Item 4.2 was revised: “Training related to clinical trials” was replaced by “human research,” and examples were added. 3. 修改 4.2 及 14.註：2 人體試驗管理辦法版次。 3. 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.”	20170709

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適用單位 Applied to	□全院 □All units in the hospital ■其他，並請註明：人體研究倫理審查委員會 ■Other (Please specify): The IRB Committees		

版次 Version	頁數 No. Page	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
E	19	1. 修改 10.2.4 表單名稱。 1. The wording of the title of item 10.2.4 was revised. 2. 修改第 12 項之子編號。 2. Revised the sub-numbers of item 12. 3. 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。” 3. Revised item 12.4 to be “On the order of the central authority, manufacturer or principal investigator, stop the execution of study.” 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. 5. 刪除原 12.6 內容。 5. Delete original contents of item 12.6. 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.	20190527
F	19	1. 文字校訂。 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.”	20210528

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版次 Version	頁數 No. Page	文件修訂摘要 Summary of Revisions of the Document	實施日期 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.”	20210528
G	19	1. 修改 9.2 審查期限：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.”	20211209
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H	20	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. 增加醫療器材臨床試驗之主持人資格條件。 2. Increased the qualification requirements for the Principal Investigator of medical device clinical trials.	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-工作常規-3001 IRB-Regulations of Operation-3001	文件名稱 Title	名詞解釋與定義作業指導書 SOP for Definitions
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。

※**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。

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").

2.2 委員的組成須符合以下需求：

2.2 Composition of the IRB should meet the following requirements:

2.2.1 具備專業技術和經驗，足以審查研究計畫。

2.2.1 IRB members should have sufficient expertise and experience to review research protocols

2.2.2 需考量種族、性別和文化背景。

2.2.2 Ethnicity, gender and cultural background should be taken into account.

2.2.3 具備對社區和病患族群態度之敏感度。

2.2.3 IRB members should be sensitive to community attitudes and patient groups.

2.2.4 具備相關法規、醫療專業和倫理的知識。

2.2.4 IRB members should have sufficient knowledge about relevant laws and regulations, medical expertise, and ethics.

2.2.5 應迴避任何有利益相關之計畫審查程序。

2.2.5 IRB members should not participate in the review of studies in which they have conflicts of interest.

2.2.6 應無性別歧視。

2.2.6 IRB members should not discriminate against any gender.

2.3 委員類別

2.3 Types of IRB Members

2.3.1 非生物醫學科學背景委員：為法律專家、社會工作人員及其他社會公正人士等非生物醫學相關領域之委員。

2.3.1 Members without biomedical science backgrounds: Legal experts, social workers, and other impartial citizens who do not have biomedical science backgrounds.

2.3.2 生物醫學科學背景委員：指生物醫學相關領域之專業人士。

2.3.2 Members with biomedical science backgrounds: Professionals in fields related to biomedical science.

3.院外人體試驗計畫的審查

3. Review of Research from Outside TCVGH

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。

3.1 The IRB may accept protocol submissions of clinical trials by specific institutions outside TCVGH and conduct review according to IRB regulations.

3.2 特定院外機構之人體試驗計畫案包含：

3.2 The above-mentioned protocols submitted by specific institutions outside TCVGH include:

3.2.1「榮民醫療體系垂直整合」政策之中區榮院研究計畫，可由該機構擔任計畫主持人，且須有確實聯絡人以便聯繫。

3.2.1 Research conducted by another veterans hospital in central Taiwan under the policy of “Vertical Integration of Veterans Hospitals.” The PI may be affiliated with the research site outside TCVGH, and the contact information of a contact person should be provided.

3.2.2 與本院有合作研究之各大專院校送審之研究計畫。

3.2.2 Research proposed by a college or university which has signed an MOU with TCVGH.

3.2.3 於本院執行之院外機構研究計畫。

3.2.3 Research proposed by an external institution but conducted in TCVGH.

4.計畫主持人

4. Principal Investigator (PI)

4.1 負責執行和協調研究計畫的專業人員，包含共同主持人；研究團隊可包括其他組成。

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.

4.2 須依規定接受人體研究相關訓練（如：研究倫理、法律、臨床試驗及 GCP 等訓練），3 年內達 6 小時以上。

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 日衛生福利部衛部醫字第 1051662154 號令修正公告）：

(In compliance with the Regulations on Human Trials (amended and promulgated on 14 April 2016 by the Ministry of Health and Welfare, pursuant to Wei-Bu-Yi-Zi No. 1051662154):

第二條：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，應施行人體試驗研究。

Article 2: A human trial research (hereinafter “Human Trial” 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.

第四條：主持人應具下列資格：

Article 4: The trial conductor [PI] referred to in the preceding article shall possess the following qualifications:

一、 領有執業執照並從事臨床醫療五年以上之醫師、牙醫師或中醫師。

1. Being a licensed physician, dentist, or traditional Chinese medicine physician with five (5) or more years of experience in clinical treatment.

二、最近六年曾受人體試驗相關訓練三十小時以上；於體細胞或基因治療人體試驗之主持人，另加五小時以上之有關訓練。

2. Having received human trial related training of more than thirty (30) hours within the past six (6) years; being the trial

conductor in Human Trials of somatic cells or gene therapy with additional five (5) or more hours of relevant training.

三、最近六年研習醫學倫理相關課程九小時以上。

3. Taking medical ethics related courses for more than nine (9) hours within the past six (6) years.

曾受醫師懲戒處分，或因違反人體試驗相關規定，受停業一個月以上或廢止執業執照處分者，不得擔任主持人。】

Those who have been subject to physician disciplinary or whose licenses have been suspended for more than one (1) month or abolished due to any violation of laws and regulations related to Human Trials shall not serve as a trial conductor.)

【依「醫療器材優良臨床試驗管理辦法」（2021 年 04 月 09 日衛生福利部衛授食字第 1101601721 號令訂定公告）：

(In compliance with the Regulations on Good Clinical Practice for Medical Devices (promulgated on 09 April 2021 by the Ministry of Health and Welfare, pursuant to Wei-Shou-Shi-Zi No. 1101601721):

第 27 條：試驗主持人，應具備下列資格及條件：

Article 27: An investigator shall possess the following qualifications:

一、領有執業執照，並從事臨床醫療五年以上之醫師。但依本法第三十七條第一項但書公告無顯著風險之臨床試驗，得以領有中央主管機關核發之師類醫事人員專門職業證書，且實際從事五年以上相關專業工作者為之。

1. Being a licensed physician with 5 or more years of experience in clinical treatment. However, according to Paragraph 1, Article 37 of this Act, clinical trials that do not involve significant risks may be conducted by professional medical personnel who hold a medicine-related professional certificate of the specialist category issued by the Competent Authority and have engaged in related practice for 5 years or more.

二、最近六年曾受臨床試驗相關訓練三十小時，且至少包括醫療

器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.

4.2.3 具 N3 證書且為大學（含）以上學歷者。

4.3.3 Holding an N3 certificate and a bachelor's or higher degree.

4.2.4 須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任協調人。

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

6. Documents of Research 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").

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。

10.1 When a study is completed, the PI should submit a closing report to the IRB.

10.2 結案資料應包含：

10.2 Study closure documents should include:

10.2.1 結案報告表/PTMS 結案申請書（系統文件不列入附件）。

10.2.1 Closing Report Form/PTMS Study Closure Application Form (the electronic file in the system is not listed as an appendix).

10.2.2 受試者清單與收案狀況描述表。

10.2.2 List of Subjects and Description of Enrollment.

10.2.3 若試驗計畫必須取得受試者同意書，則應繳交受試者同意書及受試者勾選項目頁面影本。

10.2.3 If the protocol requires subjects to sign an ICF, photocopies of a complete copy of the ICF (as a sample), and cover pages and signatures of all other subjects with checklists for the subjects to complete (if required) must be submitted to the IRB.

10.2.4 嚴重不良事件通報紀錄表(僅通報 SUSAR)。

10.2.4 Serious Adverse Event Report Form (only SUSAR is reported).

10.2.5 其他。

10.2.5 Others.

11.試驗暫停 (Suspension)

11. Protocol Suspension

IRB 依下列規定得先行電話、再以書面通知主持人暫停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暫停報告。「試驗暫停」則是有可能重啟試驗之進行。

In the following conditions the IRB staff may contact the PI to suspend a study in progress first by phone and then by writing, and request the PI to submit a protocol suspension report within

14 working days. A suspended protocol may be reopened.

11.1 經 IRB 查核，發現有違反計畫書執行內容。

11.1 If protocol violation is discovered during IRB review or monitoring, the study will be suspended.

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.

12.2 違反現行法律、醫學倫理和人體試驗相關規範者。

12.2 A study may be terminated if it violates the law, medical ethics, or clinical trial regulations.

12.3 經中央主管機關、廠商或主持人來文通知停止執行之計畫。

12.3 A study is terminated if the central competent authority, the sponsoring company, or the PI informs the IRB by writing that the study should be terminated.

13.試驗結束

13. Termination of a Suspended Study

主持人接獲試驗暫停通知並未於限期內修正或回覆，則 IRB 會得於大會中討論並決議終止其試驗。

If the PI does not respond or make appropriate changes within the requested deadline after having received the notification of protocol suspension, the IRB may discuss the protocol in a board meeting and determine to terminate the study.

14.已結案之研究檔案

14. Records of a Closed Study

已結案之人體試驗各相關文件，須建檔備存。

All records and documents related to a closed clinical trial should be filed and retained by the IRB as follows:

14.1 計畫書、計畫書修正版、受試者同意書、受試者同意書修正版、招募廣告、計畫主持人和研究地點資料等。

14.1 Protocol, amended protocol, ICF, amended ICF, recruitment advertisement, information on the PI and research site.

14.2 各項紀錄包含與計畫主持人之溝通紀錄與信函。

14.2 All records including communication log and correspondence with the PI.

14.3 各項報告，含進度報告、試驗新藥之安全報告、受試者傷害報告、科學評估等。

14.3 All reports including progress report, safety report of study drug, report of harm, and scientific assessment.

14.4 已結案之研究檔案須在結案後至少保存三年，以供參考備查，並妥善保管於檔案室中(詳見 IRB-本會-工作常規-2020 檔案維護管理程序書)。

14.4 Research documents of a closed study should be retained properly in the IRB Archive for at least three years for future reference (refer to the document titled “IRB-Regulations of Operation-2020-SOP for Document Management”).

註：

Note:

1. 「藥品優良臨床試驗作業準則」(民國 109 年 08 月 28 日修正)之第 29 條規定：「人體試驗委員會應保存書面作業程序、委員名單、委員職業及聯繫名單、送審文件、會議紀錄、信件、及其他臨床試驗相關資料至試驗結束後三年，且可供主管機關隨時調閱」。

1. According to Article 29 of the Regulations for Good Clinical Practice (amended on 28 August 2020), “The Ethics Committee should retain written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, correspondence and any other relevant records for a period of at least 3 years after completion of the trial and make them available upon request from the Competent Authority.”

2. 「人體試驗管理辦法」(2016 年 04 月 14 日衛生福利部衛部醫字第 1051662154 號令修正公告第 10 條規定：「審查會應將人體試驗計畫、會議紀錄、查核紀錄等相關文件，保存至人體試驗完成後至少 3 年」。

2. According to Article 10 of the Regulations on Human Trials (amended on 14 April 2016 and promulgated by the Ministry of Health and Welfare, pursuant to Wei-Bu-Yi-Zi No. 1051662154), “The Review Board shall preserve the relevant documentation, such as Human Trial proposal, meeting

minutes, or audit records for at least three(3) years after the completion of a Human Trial."

15.會議紀錄

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.

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.

15.3.4 主席、出席和列席人員姓名。

15.3.4 Names of the chair, voting members, and non-voting attendees.

15.3.5 紀錄人員姓名。

15.3.5 Name of the recording secretary.

15.3.6 報告事項之案由、內容和其決定。

15.3.6 The cause, content, and resolution of each report item.

15.3.7 計畫審查案之案由、討論內容和其投票結果與附帶決議。

15.3.7 The content, rationale, discussion, voting result and resolution of each reviewed protocol.

15.3.8 會議提案及其決議。

15.3.8 Motions and resolutions.

15.3.9 臨時動議及其決議。

15.3.9 Motions in other business and resolutions.

15.3.10 其他應行記載之事項。

15.3.10 Other items that should be recorded.

16.法定人數

16. The Quorum of a Meeting

為召開 IRB 會議及做成決議所需之最低出席人數。開會法定人數為二分之一以上委員出席，並符合衛生福利部有關名額組成與性別之規定，即其中至少一名生物醫學科學背景委員、一名非生物醫學科學背景委員、一名院外委員、非單一性別。會議表決採匿名多數決為原則，但參與投票之委員須在會議進行討論和表決時全程在場。

A quorum refers to the minimum number of members that must be present for an IRB meeting to convene and for resolutions to be made. The quorum of a meeting should be half of the members plus one, and the composition of attending members should comply with the regulations by the Ministry of Health and Welfare: There should be at least one member with a biomedical science

background, one member without a biomedical science background, one member not affiliated to TCVGH, and both men and women should be present. Voting in the meeting adopts the principle of majority in anonymity. All voting members should be present during the entire discussion and voting process.

17.新計畫案

17. New Protocol

17.1 指首次送交委員會審核之人體試驗計畫案，內容包括計畫書、受試者同意書、主持人資格文件、藥品或醫療器材相關資料和招募廣告等。

17.1 A new protocol refers to a clinical trial protocol submitted to the IRB for review for the first time. The submission should include the protocol, ICF, documents about the qualifications of the PI, relevant information about the study drug or medical device, and recruitment advertisement.

17.2 新計畫案亦包括過去未獲核准之再申請案。

17.2 A new protocol may also refer to a re-submitted protocol which was not approved by the IRB.

18.追蹤審查報告

18. Continuing Review Report

18.1 一年型計畫之主持人於計畫執行許可書核發日起一年內繳交進度報告或結案報告。

18.1 The PI of a one-year research project should submit a progress report or a closing report within one year after the issuance of the Certificate of Approval.

18.2 多年型計畫，計畫主持人須於計畫執行許可書到期前繳交進度報告，以獲得人體研究倫理審查委員會核准計畫之展延。

18.2 The PI of a multi-year project should submit a progress report before the Certificate of Approval expires in order for the research extension to be approved by the IRB.

18.3 承辦人員會定期提醒主持人繳交此報告。

18.3 The IRB staff member will periodically remind the PI to submit the above-mentioned report.

18.4 委員會得酌情要求更頻繁的報告次數。

18.4 The IRB may require the PI to submit reports more frequently depending on the situation.

19.計畫執行許可書之展延

19. Extension of the Certificate of Approval

計畫未能於該年度如期完成，且計畫執行許可書即將到期，主持人應於到期日二個月前主動申請展延。

The PI may request for extension two months before the Certificate of Approval expires if the study will not be completed on time.

20.計畫案修正

20. Protocol Amendment

計畫獲委員會核准後，主持人如欲變更任何計畫內容，均須向委員會申請核准後，方可依照變更後之計畫執行。

Once a protocol is approved by the IRB, the PI should apply for IRB permission if changes are to be made in the protocol. The changes may not be implemented before the IRB approves them.

21.新藥

21. New Drug

藥事法第 7 條（新藥之定義）:「係指經中央衛生主管機關審查認定屬新成分、新療效複方或新使用途徑製劑之藥品。」

According to Article 7 of the Pharmaceutical Affairs Act, “[t]he term ‘new drugs’ as used in this Act shall refer to drugs which are of the preparations having new compositions, new therapeutic compounds or new method of administration as verified and recognized by the central competent heath authority.”

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

health, safety or welfare.

24.2 可能嚴重危及受試者健康、安全或福利之生命支持系統。

24.2 It is life support equipment that may seriously threaten the subject's health, safety or welfare.

24.3 用於疾病之診斷、治療、緩解、處置或預防，可能嚴重危及受試者健康、安全或福利者。

24.3 The device is used in diagnosing, curing, alleviating, treating or preventing a disease and may seriously threaten the subject's health, safety or welfare.

24.4 其它可能嚴重危及受試者健康、安全或福利者。

24.4 Other medical device that may seriously threaten the subject's health, safety or welfare.

25.最低風險

25. Minimal Risk

指受試者可能遭遇的風險不會大於每天生活所會遇到的風險，或不會大於常規的檢驗或檢查所會遇到的風險。

"Minimal risk" means that the risk posed to the subject is not greater than that encountered in daily life or during the performance of routine examinations or tests.

26.易受傷害族群

26. Vulnerable Populations

為未成年人、受刑人、原住民、孕婦、身心障礙、精神病患、或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）。

"Vulnerable populations" refers to children, prisoners, indigenous people, pregnant women, persons with physical or mental disabilities, persons with psychiatric disorders, or other persons with limited decision-making capacity (due to lack of financial resources, lack of education, emergency situations in which the

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

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 承辦人員。

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

approval.

29.IRB 標準化文件內文之「/」符號，代表之意義為「或」。

29. In a standardized document, a slash (/) is used to mean “or.”

30.附件
無。

30. Appendix
None.