



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-2008 IRB-Regulations of Operation-2008 | 文件名稱 Title | 判定人體研究及免審案件管理程序書 SOP for Human Research Determination and Exempt Review |
| 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 | <input checked="" type="checkbox"/> 普通 <input type="checkbox"/> 密件 <input type="checkbox"/> 極機密 <input checked="" type="checkbox"/> Unclassified <input type="checkbox"/> Confidential <input type="checkbox"/> Highly Confidential |
| 適用單位 Applied to | <input type="checkbox"/> 全院 <input type="checkbox"/> All units in the hospital <input checked="" type="checkbox"/> 其他，並請註明：人體研究倫理審查委員會 <input checked="" type="checkbox"/> 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 | 5 | 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 | 修改計畫書名詞為「人體研究/試驗計畫書」。 Revised the title of the protocol to "Human Research/Clinical Trial Protocol." | 20150922 |
| D | 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. 新增「人體研究計畫免倫理審查證明書」及人體研究計畫「得免倫理審查委員會審查」評估表」：5.5、5.7、附件 6.2、6.3。 2. Added "Certificate of Exemption from IRB Review" and "Evaluation Form of Exemption from IRB Review" for human research protocols in items 5.5, 5.7 and Appendices 6.2, 6.3. | 20160318 |
| E | 4 | 抽換附件 6.2 人體研究計畫免倫理審查證明書。 Replaced Appendix 6.2 Certificate of Exemption from IRB Review | 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 |
| F | 8 | 修改附件 6.1、6.3。 Replaced Appendices 6.1, 6.3. | 20181026 |
| G | 8 | 修改附件 6.1、6.2。 Replaced Appendix 6.1, 6.2. | 20201117 |
| H | 8 | 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". 3. 本會編號增加 C 項：第三人體研究倫理審查委員會。 3. IRB number was added the term of C: The Third IRB Committee 4. 修改附件 6.1、6.2、6.3。 4. Replaced Appendices 6.1, 6.2, 6.3. | 20220920 |
| | | 本欄空白，接續下頁。 Blank. Continued on next page. | |



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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 |
| I | 8 | 1. 更改文件名稱。 1. The title of the document was revised. 2. 依據 AAHRPP 國際認證之建議修改 5.4.1。 2. According to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) was revised Item 5.4.1. 3. 修改附件 6.1 3. Replaced Appendix 6.1. | 20230717 |
| J | 8 | 1. 刪除原 5.2.2 項。 1. Deleted the original Item 5.2.2. 2. 修改原 5.2.3 ~ 5.2.4 之標號。 2. Item numbers were revised from 5.2.3 to 5.2.3. 3. 修改 5.2.1、5.3.1.1 之文字內容。 3. The wording of item 5.2.1 and item 5.3.1.1 were revised. 4. 修改附件 6.1 4. Replaced Appendix 6.1. | 20250910 |
| 訂修廢 Composed/Revised/Deleted | | 審核 Reviewed | 核准 Approved |
| <p style="color: blue; font-size: 1.2em;">本文件已經權責主管正式核准，</p> | | | |

※管制文件不得擅自塗改及做註號並禁止影印。
 ※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.





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管制文件訂修廢會審單

Review Form of Composition and Revisions of Controlled Documents

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| 文件編號 Document Number | IRB-本會-工作常規-2008 IRB - Regulations of Operation-2008 | 文件名稱 Title | 判定人體研究及免審案件管理程序書 SOP for Human Research Determination and Exempt Review |
| 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. | | |

※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.



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1. 目的

本管理程序書之目的是提供處理「得免倫理審查委員會審查之人體研究」案件（以下簡稱免審）之指引，參照 101 年 07 月 05 日衛署醫字第 1010265075 號公告「得免倫理審查委員會審查之人體研究案件範圍」訂定。

1. Purpose

The purpose of this SOP is to provide guidance for processing protocols qualified for exemption from IRB review (also referred to as “exempt review”), in accordance with “The Scope of Exemption Categories for IRB Review” announced by Ministry of Health and Welfare on 5 July 2012, pursuant to Wei-Shu-Yi-Zi No. 1010265075.

2. 適用範圍

審查項目：免審計畫案。

2. Scope

Review Category: Exempt Review Protocols

3. 參考文件

3. References

3.1 人體研究法第 4 條第 1 款：「人體研究（以下簡稱研究）：指從事取得、調查、分析、運用人體檢體或個人之生物行為、生理、心理、遺傳、醫學等有關資訊之研究」。

3.1 According to Article 4, Paragraph 1 of Human Subjects Research Act, “Human subject research (hereinafter “research”): refers to research that involves obtaining, investigating, analyzing, or using human specimens or an individual person’s biological behavior, physiological, psychological, genetic or medical information.”

3.2 行政院衛生福利部於 101 年 3 月 22 日衛署醫字第 1010064538 函說明二解釋人體研究：「尚不包括社會行為研究（即研究人與外界社會接觸時，因人際間彼此影響產生交互作用）及人文科學



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研究（即以觀察、分析、批判社會現象及文化藝術之研究）」。

3.2 According to the letter of explanation issued by the Ministry of Health and Welfare on 22 March 2012, pursuant to Wei-Shu-Yi-Zi No. 1010064538, “[Human subjects research] does not include research on social behaviors (i.e. studies about interactions which occur when humans are in contact with other humans or society) or social science (i.e. studies involving observing, analyzing, and critiquing social phenomena, culture, or the arts).”

3.3 行政院衛生福利部於 101 年 07 月 05 日衛署醫字第 1010265075 號公告「得免倫理審查委員會審查之人體研究案件範圍」訂定。

3.3 “The Scope of Exemption Categories for IRB Review” announced by Ministry of Health and Welfare on 5 July 2012, pursuant to Wei-Shu-Yi-Zi No. 1010265075.

3.4 行政院衛生福利部於 102 年 4 月 18 日衛署醫字第 1020270485 號函有關「得免倫理審查委員會審查之人體研究案件範圍」（以下稱得免審範圍）第 3 點及第 5 點疑義。

3.4 Letter of clarification issued by the Ministry of Health and Welfare on 18 April 2013, pursuant to Wei-Shu-Yi-Zi No. 1020270485, on items 3 and 5 of “The Scope of Exemption Categories for IRB Review” (also referred to as the Scope of Exempt Review).

4. 名詞定義

無。

4. Definition

None.



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5. 作業內容

5. Procedure

5.1 免審案件管理流程圖

5.1 Flow Chart of Exempt Review

| 流程 Flow Chart | 權責 Responsible Personnel | 相關文件 Relevant Documents |
|---|--|--|
| <pre> graph TD A([受理送審文件 Acceptance of Submissions]) --> B{送審文件確認 Confirmation of Submissions} B -- No --> A B -- Yes --> C[判定符合免審 Decision on Exempt Review] C --> D[發函 Issuance of Certificates] D --> E[提交大會核備 Submission to IRB Board Meeting] E --> F([紀錄保存 Records Retention]) </pre> | 承辦人員 Staff Members | 免審計畫案/人體研究計畫免審申請書/ 送審文件檢核表 Exempt Review Protocol/Exempt Review Application Form/Protocol Submission Checklist |
| | 承辦人員 Staff Members | 免審申請書/中文計畫書/摘要/利益迴避/ 保密聲明書/履歷資料/人體研究訓練證明影本 Exempt Review Application Form/ Protocol and Abstract in Chinese/ Conflict of Interest Statement/ Confidentiality Statement/CVs/ Photocopies of Human Research Training Certificates |
| | 執行秘書/ (副)主任委員 Executive Secretary/ (Vice) Chair | 人體研究法/衛署醫字第 1020270485 號函/ 人體研究計畫免審申請書/ 人體研究計畫「得免倫理審查委員會審查」評估表 Human Subjects Research Act/Letter of Clarification (Wei-Shu-Yi-Zi No. 1020270485)/Application Form of Protocol for Exempt Review/Evaluation Form of Exemption from IRB Review |
| | 承辦人員 Staff Members | 研究計畫免審公文/ 免審許可書 Notification of Exempt Review Protocol/ Certificate of Exemption from IRB Review |
| | 承辦人員/ 出席委員 Staff Members/ Attendees | 會議紀錄 Meeting Minutes |
| | 承辦人員 Staff Members | 免審計畫案/研究計畫免審公文/ 人體研究計畫免倫理審查證明書 Exempt Review Protocol/ Notification of Exempt Review Protocol/ Certificate of Exemption from IRB Review |



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5.2 受理送審文件

5.2 Acceptance of Submissions

5.2.1 主持人確認非為人體研究，在PTMS系統提出免審案件申請。

5.2.1 The principal investigator shall confirm that the protocol is not human subjects research and submit the application for exempt review in the PTMS system.

5.2.2 由承辦人受理後，依照「送審文件檢核表」核對文件是否齊備。

5.2.2 After staff members have received the application, they shall check if all documents are submitted according to the “Protocol Submission Checklist.”

5.2.3 於本會管理系統建檔新計畫案編號及相關內容，以便日後進行審查進度追蹤。

5.2.3 Staff members shall create an electronic folder in the IRB protocol management system with a new IRB number and relevant information in order to follow up on the progress of review.

5.3 送審文件確認

5.3 Confirmation of Submissions

5.3.1 承辦人員確認下列資料之完整性：

5.3.1 Staff members shall confirm the completeness of the following documents:

5.3.1.1 人體研究計畫免審申請書/PTMS申請書。

5.3.1.1 Certificate of Exemption from IRB Review / Certificate of PTMS.

5.3.1.2 中文摘要。

5.3.1.2 Abstract in Chinese

5.3.1.3 人體研究/試驗計畫書。

5.3.1.3 Human Research/Clinical Trial Protocol



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5.3.1.4 計畫主持人利益迴避聲明書。

5.3.1.4 Conflict of Interest Statement by the Principal Investigator

5.3.1.5 研究成員保密聲明書、最新履歷資料人體研究相關教育訓練時數證明。

5.3.1.5 Confidentiality Statement by Research Member, updated CVs and relevant proof of sufficient hours of human research training.

5.3.2 承辦人員核對若發現有遺漏文件，通知主持人補件。

5.3.2 Staff members shall notify the PI to submit missing documents.

5.3.3 行政審查確認後，應依照如下規範，給予計畫案本會編號，並建立專屬計畫檔案及資料夾。

5.3.3 Upon completion of the administrative review of protocol submissions, staff members shall assign each protocol submission with an IRB number and set up a designated folder for all relevant files of the protocol.

| 碼別 Digit | 第一碼 1st | 第二碼 2nd | 第三、四碼 3rd & 4th | 第五至七碼 5th to 7th | 第八碼 8th |
|--|---|-----------------------------|---------------------------------------|-------------------------|--|
| 代表意義 Meaning of the digit | 案件性質 Type of protocol | 審查程序 Review category | 新案 受理年份 Year of submission | 流水號 Serial number | 人體研究倫理 審查委員會 編號 IRB Committee |
| 代碼意義 Meanings of letter codes | J：JIRB 案件 J: JIRB S：有合作廠商 S: Collaboration with a company C：院內自行研究 C: Research within TCVGH N：國衛院案件 N: Research from the National Health Research Institutes (NHRI) | W：免審 W: Exempt review | 西元年 Last two digits of the year | 001 至 999 001 to 999 | A：第一人體研 究倫理審查委 員會 A: The First IRB Committee B：第二人體研 究倫理審查委 員會 B: The Second IRB Committee C：第三人體研 究倫理審查委 |



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| | | | | | 員會 C: The Third IRB Committee |
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5.4 判定符合免審

5.4 Decision on Exempt Review

5.4.1 決定研究是否涉及人類受試者以及免審。

5.4.1 Decision on whether an activity is research involving human subject, and exempt review.

5.4.1.1 執行祕書、(副)主任委員決定一項活動是否涉及人類受試者。

5.4.1.1 The Executive Secretary and the (Vice) Chair shall make determination whether an activity involves human subjects.

5.4.1.2 執行祕書、(副)主任委員按「人體研究法」第5條之規定，依主管機關公告得免審查之研究案件範圍者「免予審查」。

5.4.1.2 The Executive Secretary and the (Vice) Chair shall decide whether a protocol is qualified for exempt review in accordance with Article 5 of “Human Subjects Research Act” and “The Scope of Exemption Categories for IRB Review” announced by the central competent authority.

5.4.2 依主管機關公告 102 年 4 月 18 日衛署醫字第 1020270485 號函「得免倫理審查委員會審查之人體研究案件範圍第 3 點及第 5 點疑義」，研究對象若為未成年人、收容人、原住民、孕婦、身心障礙者，不得列為「免審範圍」。

5.4.2 According to the letter of clarification on items 3 and 5 of “The Scope of Exemption Categories for IRB Review” issued by the central competent authority on 18 April 2013, pursuant to Wei-Shu-Yi-Zi No. 1020270485, if the research subjects are minors, prisoners, indigenous people, pregnant women, or individuals with physical or mental disabilities, the protocol shall not be in the “exempt review”



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category.

5.4.3 本會對於案件是否「得免倫理審查委員會審查」保有最後審核權。不符合免審條件者，則另案送審。

5.4.3 The IRB of TCVGH has the final say on whether a protocol is qualified for exemption from IRB review or not. Protocols not qualified for exempt review shall be submitted again for review.

5.5 發函

免審查案評估同意後，由承辦人員開立「免送人體研究倫理審查委員會審查公文」及「人體研究計畫免倫理審查證明書」。

5.5 Issuance of Certificates

After a protocol has been approved for exempt review, staff members shall issue the “Notification of Exempt Review Protocol” and “Certificate of Exemption from IRB Review.”

5.6 提交大會追認後核備

判定為同意「免送人體研究倫理審查委員會」者，須提報大會追認後核備。

5.6 Submission to IRB Board Meeting for Recordation

Protocols approved to be exempt from IRB reviews shall be submitted to IRB board meetings for recordation.

5.7 紀錄保存

相關人員應依據如下規定，妥善保存各項紀錄。

5.7 Records Retention

Relevant personnel should keep all records carefully following the guidelines below.

| 編號 Number | 紀錄名稱 Name of Document | 保存地點 Retention Location | 保存期限 Retention Period |
|--------------|--|----------------------------|--------------------------|
| 1 | 人體研究計畫免審申請書 Exempt Review Application Form | IRB 檔案室 IRB Archive | 3 年 3 years |
| 2 | 人體研究計畫免倫理審查證明書 Certificate of Exemption from IRB Review | IRB 檔案室 IRB Archive | 3 年 3 years |



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| 3 | 人體研究計畫「得免倫理審查委員會審查」評估表 Evaluation Form of Exemption from IRB Review | IRB 檔案室 IRB Archive | 3 年 3 years |
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6. 附件

6. Appendices

6.1 人體研究計畫免審申請書

6.1 Exempt Review Application Form

6.2 人體研究計畫免倫理審查證明書

6.2 Certificate of Exemption from IRB Review

6.3 人體研究計畫「得免倫理審查委員會審查」評估表

6.3 Evaluation Form of Exemption from IRB Review