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-2016 IRB-Regulations of Operation-2016	文件名稱 Title	試驗偏離/背離的處理管理程序書 SOP for Protocol Deviation/Violation
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. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
A	20	新訂。Newly composed.	20140519
B	6	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 Standard Operating Procedure of the Human Research Committee."	20150119
C	6	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.The list of relevant documents was revised in item 5.1 Flow Chart. 3.新增 5.2.3 計畫主持人超過通報期限之相關規定。 3.Item 5.2.3 was added regarding regulations about the time limit.	20160318
D	6	1.修改 5.1 流程圖「試驗偏離案申請」、「遴選審查委員」之權責，並修改 5.2.2 試驗偏離/背離初步評估及 5.4 遴選審查委員之權責。 1.Responsible personnel for "protocol deviation reporting" and "selection of reviewers" was revised in item 5.1 Flow Chart; item 5.2.2 was revised regarding initial assessment of protocol deviation/violation; responsible personnel for selecting reviewers was revised in item 5.4. 2.修改 5.5：刪除「若有意見，得以另紙繕寫(打)審查意見」之字句。 2. The following sentence was deleted from item 5.5: Further review comments (if any) may be written on a separate piece of paper. 3.修改 5.6.1 轉交審查委員意見之方式：新增電子檔。 3. The way of sending reviewers' comments was revised in item 5.6.1: "Electronic file" was added. 4.修改 5.7.4.2：將「主持人接受教育訓練」修正為「研究相關人員接受教育訓練」。 4. Item 5.7.4.2 was revised: "The PI should receive training" was replaced by "research personnel should receive training." 5.修改抽換附件 6.1、6.2、6.3。 5. Appendices 6.1, 6.2, and 6.3 were replaced.	20170709

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E	10	1. 刪除 5.2.3。 1. Deleted item 5.2.3. 2. 修改 5.5：刪除「審查結束，應於「試驗偏離/背離審查意見表」簽名並簽署日期後，送回承辦人員。」 2. The following sentence was deleted from item 5.5: When the review is completed, the reviewer should sign and date on the "Protocol Deviation/Violation Review Form" and submit the form to the IRB staff. 3. 修改 5.6.1：新增計畫主持人回覆期限。 3. Item 5.6.1 was revised: "The due date for the PI to respond to reviewers' comments" was added. 4. 修改 5.7.1：承辦人員必須將所有之試驗偏離/背離事件列入大會議程，並將計畫偏離/背離的詳細情況提大會討論/核備。 4. Item 5.7.1 was revised: Staff members should place all incidents of protocol deviation/violation on the board meeting agenda and submit details of the incidents to the board for discussion/review. 5. 5.7.4.6 其他項增加說明文句：(如：請贊助廠商/CRO 提出改善計畫或訓練證明)。 5. The following was added to item 5.7.4.6 Other: (e.g. requiring the sponsoring company/CRO to submit an improvement plan or relevant training certificates). 6. 抽換附件 6.1、6.2。 6. Appendices 6.1 and 6.2 were replaced.	20190527
F	15	1. 依據 AAHRPP 國際認證委員之建議進行增修。 1. The following modifications were made according to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) reviewers. 2. 新增參考文件 3.1:「人體研究法」總統華總一義字第 10000291401 號令制定公布全文 26 條，民國 100 年 12 月 28 日施行。 2. Added Item 3.1 Human Subjects Research Act, promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 100002914011 dated 28 December 2011 3. 新增 4.1「不遵從事件(Non-compliance) 」之定義。 3. Added Item 4.1: The definition of "Non-compliance". 4. 新增 4.2 不遵從事件嚴重程度評估。 4. Added Item 4.2: Severity assessment of Non-compliance.	20191018

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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		

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F	15	5. 新增 4.2.1「輕微不遵從(Minor Non-compliance) 」之定義。 5. Added Item 4.2.1: The definition of "Minor Non-compliance". 6. 新增 4.2.2「嚴重不遵從(Serious Non-compliance) 」之定義。 6. Added Item 4.2.2: The definition of "Serious Non-compliance" 7. 新增 4.2.3「持續性不遵從(Continuing Non-compliance) 」之定義。 7. Added Item 4.2.3: The definition of “Continuing Non-compliance”. 8. 新增 5.5.1：委員審查通報事件，依事件情節判定為輕微/嚴重或持續性不遵從。必要時，可請主持人提供更詳細資訊。審查建議得為「請主持人回覆」、「提大會請委員討論」或「於大會核備後存查」。 8. Added Item 5.5.1: When reviewing the notified incident IRB members shall determine the severity of the incident as Minor/Serious or Continuing Non-compliance based on the circumstance. If necessary, the IRB shall ask the principal investigator to provide further details. The IRB members shall recommend one of the following suggestions: "request the PI to respond", "sent to the full board for discussion" or "submit to the full board for confirmation". 9. 新增 5.5.2：若委員認定為輕微或非持續性不遵從，委員將審查是否需要有改善措施。若有，將建議或請主持人提出改善措施，並於回覆後送原審委員複審是否同意，審查結果存查，排入大會進行核備；若不同意則建議再提會討論。 9. Added Item 5.5.2: In the case that an incident has been determined as Minor or non-continuous Non-compliance, IRB members shall determine whether improvement measures are needed. If yes, the principal investigator shall be asked to respond in writing with improvement measures, and the reply shall be sent to the original reviewers for review and approval. The results of the review shall be recorded in the IRB board meeting documents and passed to the IRB board meeting for verification. In the case that the reviewers are not satisfied with the reply of the principal investigator, the case will be passed to the next IRB board meeting for discussion.	20191018

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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. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
F	15	10.新增 5.5.3：若委員判定屬嚴重或持續性不遵從，則需提大會討論。 10.Added Item 5.5.3: If the case is determined to be Serious or Continuing Non-compliance by the reviewer, it needs to be discussed in the IRB board meeting. 11.新增 5.7.4.1「輕微且非持續性不遵從」之處置方式。 11.Added Item 5.7.4.1 "Minor and non-continuous Non-compliance" management method. 12.新增 5.7.4.2「嚴重或持續性不遵從」之處置方式。 12.Added Item 5.7.4.2 "Serious or Continuing Non-Compliance" management method. 13.新增 5.7.5：若計畫案所發生的試驗偏離/背離，符合人體研究法第 17 條第二、三款之規範時，需將審查結果通知衛生福利部，並通知本院受試者保護中心。 13.Added Item 5.7.5: In the case that test deviation/violation has occurred which complies with the specifications of the second and third item of Article 17 of “Human Subjects Research Act”, the Ministry of Health and Welfare and the Human Research Protection Center at this hospital shall be notified of the results of the IRB review. 14.抽換附件 6.1。 14. Appendix 6.1 was replaced.	20191018
G	15	1. 「試驗偏離/背離案申請」之文字依衛生福利部人體研究倫理審查委員會查核作業基準修正為「試驗偏離/背離案通報」。 1. The modification was made according to the IRB Review Operations Standards of MOHW (Ministry of Health and Welfare): “The Deviation/Violation application” was replaced by “Protocol Deviation/Violation reporting.” 2. 修改 5.3 標題。 2. Item 5.3 was revised the Chinese title. 3. 修改 5.5.1、5.6.3 之內容文字。 3. The wording of item 5.5.1 and item 5.6.3 were revised.	20210528

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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		

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G	15	4. 修改 5.6.1 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。 4. Item 5.6.1 was revised the PI's reply period to 28 calendar days, and deleted the description of the extension. 5. 刪除 5.7.3。 5. Deleted item 5.7.3. 6. 修改原 5.7.4 標號為 5.7.3。 6. Changed the original item number 5.7.4 to 5.7.3. 7. 刪除 5.7.3.1 之「非持續性」字句。 7. The following words were deleted from item 5.7.3.1: non-continuous. 8. 新增 5.7.3.2.5.h 其他。 8. Added item 5.7.3.2.5.h Other 9. 刪除原附件 6.3「試驗偏離/背離審查意見表」。 9. The original Appendix 6.3 “Protocol Deviation/Violation Review Form” was deleted. 10.抽換附件 6.1 ~ 6.3。 10.Appendices 6.1 ~ 6.3 were replaced.	20210528
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H	15	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. 修改 5.5.1、5.7.3.2 之內容文字。 2. The wording of item 5.5.1 and item 5.7.3.2 were revised. 3. 刪除 5.5.2 之「或非持續性不遵從」字句。 3. The following words were deleted from item 5.5.2: or non-continuous. 4. 抽換附件 6.1 、6.3。 4. Appendices 6.1, 6.3 were replaced.	20230717
I	15	1. 5.4：執行秘書修改為（副）主任委員。 1. Item 5.4: Executive Secretary changed to (Vice) Chair.	20250910

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.

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Review Form of Composition and Revisions of Controlled Documents

文件編號 Document Number	IRB-本會-工作常規-2016 IRB-Regulations of Operation-2016	文件名稱 **Title**	試驗偏離/背離的處理管理程序書 **SOP for Protocol Deviation/Violation**

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

1. Purpose

本管理程序書描述對於經委員會審查通過之計畫案，未遵循審查通過時之計畫書內容，或未遵循本國/國際相關規範或法規進行試驗時，人體研究倫理審查委員會對主持人提出處理的程序。

The purpose of this SOP is to describe actions to be taken by the IRB when the PI fails to follow the procedures written in the IRB approved protocol, or when the PI fails to comply with relevant national and/or international law or regulations regarding research ethics.

2.適用範圍

2. Scope

承辦人員負責彙整試驗偏離或背離事件相關資料，並做成紀錄。

This SOP applies to all IRB-approved protocols. Relevant documents regarding protocol deviation or violation reports should be compiled and recorded by IRB staff.

3.參考文件

3. References

3.1「人體研究法」總統華總一義字第 10000291401 號令制定公布全文 26 條，民國 100 年 12 月 28 日施行。

3.1 Human Subjects Research Act, promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 100002914011 dated 28 December 2011

4.名詞定義

4. Definitions

4.1 不遵從事件(Non-compliance)：未能遵照人體研究倫理審查委員會所核准之計畫執行人體研究及試驗計畫案，或違反臨床試驗相關法規及本院相關規範。其類型分為：

4.1 Non-Compliance: Failure to follow the research proposal

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approved by IRB to perform human research and test plans, or violating clinical trial-related regulations and the relevant regulations of the hospital. Non-compliance can be divided into the following types:

4.1.1 試驗偏離(Deviation)：

意指計畫主持人/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人體研究倫理審查委員會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，不增加試驗的風險或對受試者之權益、安全或福祉無不良影響，並且不影響研究資料之完整性。其行為包含但不限於以下各項：

4.1.1 Protocol Deviation:

A protocol deviation is (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. In a protocol deviation incident, the risk presented to the subjects is not increased; there is no adverse effect on the subjects' rights, safety or welfare; the completeness of the research data is not affected. Protocol deviation incidents may include but are not limited to:

4.1.1.1 未依研究計畫內容所規範的時間與項目進行檢驗工作。

4.1.1.1 Examinations have not been conducted according to the time and content described in the research protocol.

4.1.1.2 未遵守研究計畫內容所規範的步驟與程序進行試驗。

4.1.1.2 The trial has not followed the procedures designed in the protocol.

4.1.1.3 抽血未告知受試者需禁食因而導致抽血行為及檢驗資料無效。

4.1.1.3 The subject was not informed that they should fast

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before blood tests, so the test results were invalid.

4.1.1.4 未依指定之時間與方法服用試驗藥物。

4.1.1.4 The time or method that the subject took the study drug did not follow the procedure in the approved protocol.

4.1.1.5 未依指定時間回診、歸還藥物或更換藥物。

4.1.1.5 The subject did not show up for return appointments or did not return the study drug as required, or the study drug was not replaced as designed in the approved protocol.

4.1.1.6 未經研究計畫主持人同意前服用其他藥物或健康食品。

4.1.1.6 The subject was taking other drugs or supplements without the permission from the PI.

4.1.1.7 未依研究計畫規範定時檢驗血糖或記錄飲食狀況。

4.1.1.7 The subject's blood glucose status or dietary intake was not recorded as required by the study design.

4.1.2 背離(Violation)：

意指計畫主持人/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人體研究倫理審查委員會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，可能增加試驗的風險或對受試者之權益、安全或福祉有不良影響，並且影響研究資料之完整性。其行為包含但不限於以下各項：

4.1.2 Protocol Violation:

A protocol violation is (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. In a protocol violation incident, the risk presented to the subjects may be increased; there may be adverse effects

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on the subjects' rights, safety or welfare; the completeness of the research data may be affected. Protocol violation incidents may include but are not limited to:

4.1.2.1 研究計畫未經人體研究倫理審查委員會審查通過前即收納受試者。

4.1.2.1 Subject enrollment began before the protocol was approved by the IRB.

4.1.2.2 未依納入條件即收納受試者。

4.1.2.2 Subject enrollment did not meet the inclusion criteria.

4.1.2.3 未依排除條件而收納受試者。

4.1.2.3 Subject enrollment did not meet the exclusion criteria.

4.1.2.4 未依照衛生福利部規定之時間與內容通報未預期嚴重不良事件 (SAE)。

4.1.2.4 The PI did not report unanticipated serious adverse events following the regulations set by the Ministry of Health and Welfare.

4.1.2.5 未依隨機原則將受試者分組或隨機分組時發生錯誤。

4.1.2.5 The grouping of the subjects did not follow the principle of random selection, or mistakes were made during the process of random selection.

4.1.2.6 未正確給予研究計畫內容所標示之藥物種類或劑量。

4.1.2.6 The type of drug or the dose given to the subjects was not accurate according to the research protocol.

4.1.2.7 給予受試者服用禁用藥物。

4.1.2.7 Prohibited drug was given to the subjects.

4.2 不遵從事件嚴重程度評估：不遵從事件情節有不同的等級-可從輕微至重大、無心的或蓄意的、僅發生一次或是發生好幾次。

4.2 Severity assessment of Non-compliance: Non-compliance is classified into minor or serious non-compliance, unintentional or intentional non-compliance, single or multiple

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non-compliance.

4.2.1 輕微不遵從(Minor Non-compliance)：

雖有違規情形，但不至於增加受試者或研究對象原先預估之風險。例如：

4.2.1.1 未通知本委員會而有研究團隊成員之異動。

4.2.1.2 縮短返診追蹤的間距。

4.2.1.3 未事先獲得本委員會之核准而小幅更改問卷內容。

4.2.1.4 其他經評估風險輕微者。

4.2.1 Minor Non-compliance:

Though violation occurs, it does not increase the originally expected risk to the trial subject or participant. For example:

4.2.1.1 Changes in the research team members without notifying the IRB.

4.2.1.2 Shortened intervals of follow up tracking.

4.2.1.3 Minor changes to the questionnaire without prior approval from the IRB.

4.2.1.4 Other risks assessed to be minor.

4.2.2 嚴重不遵從(Serious Non-compliance)：

意指試驗受試者的風險增加，試驗受試者的權利和利益受到影響，或者研究的準確性可能因違反行為而受到影響。例如：

4.2.2.1 未事先獲得委員會核准即進行介入性研究。

4.2.2.2 收納不符合納入條件的受試者參加具有風險之研究，經委員會判斷此增加該受試者之風險。

4.2.2.3 未依計畫執行知情同意過程。

4.2.2.4 對於新藥、新醫療技術、新醫療器材等臨床試驗過程的監督不周全。

4.2.2.5 未能遵守本委員會為保障受試者安全而給予的建議。

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4.2.2.6 未依規定向本委員會通報非預期問題、計畫案之變更等。

4.2.2.7 嚴重偏離計畫書內容以致增加受試者參加試驗之風險。

4.2.2 Serious Non-compliance:

The risk to the trial subject is increased, the rights and interests of the trial subject are affected or accurateness of the research may be affected due to the violation. For example:

4.2.2.1 Interventional research is conducted without prior approval from the IRB.

4.2.2.2 Subjects not meeting the inclusion criteria are enrolled in a risk-research study, a condition judged by the IRB to increase the risk of subjects.

4.2.2.3 Not implementing the informed consent process according to the proposal.

4.2.2.4 Inadequate supervision of clinical trials such as new drugs, new medical technologies, and new medical devices.

4.2.2.5 Failure to comply with the recommendations of the IRB to ensure subject safety.

4.2.2.6 Failure to notify the IRB of unanticipated problems, amendments to the protocol etc..

4.2.2.7 Marked deviations from the protocol contents which increase the risk of subjects participating in the trial.

4.2.3 持續性不遵從(Continuing Non-compliance)：

違規行為是由於研究人員不熟悉、不理會或刻意不遵守相關法規，若不採取適當措施，可能會持續出現偏差或違規。

4.2.3 Continuing Non-compliance:

The violation is committed due to the researcher's unfamiliarity with, deliberate ignorance or intentional disobedience of relevant regulations. If appropriate measures are not taken, deviations or violations may continue to occur.

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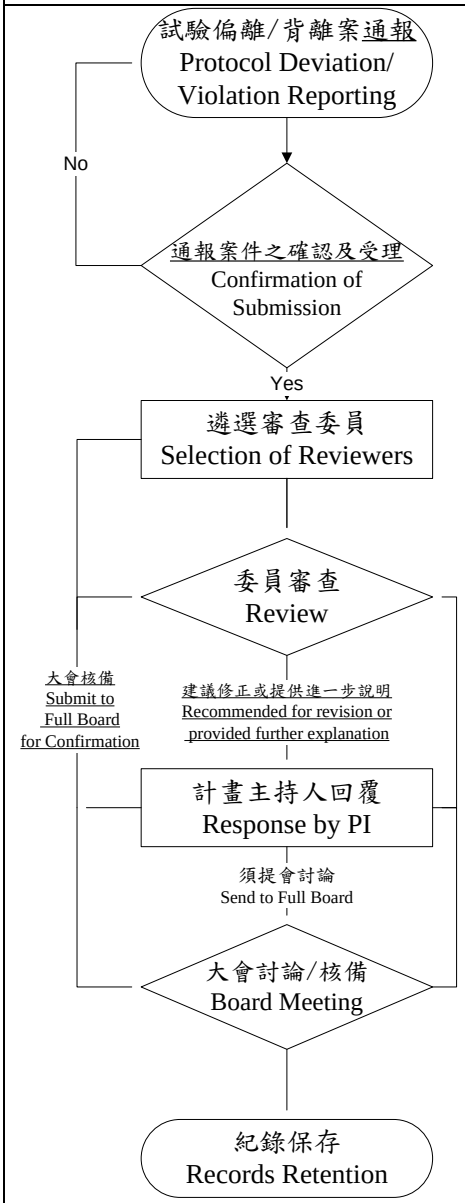
5.作業內容

5. Procedure

5.1 試驗偏離/背離的處理管理流程圖

5.1 Flow Chart of Protocol Deviation/Violation Reporting

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	計畫主持人/ 執行祕書 Principal Investigator/ Executive Secretary 承辦人員 Staff Members 執行祕書 Executive Secretary 審查委員 Reviewers 計畫主持人 Principal Investigator 委員 Reviewers 承辦人員 Staff Members	試驗偏離/背離紀錄表 Protocol Deviation/Violation Report Form 試驗偏離/背離紀錄表 Protocol Deviation/Violation Report Form 送審文件/ 偏離/背離評估表 Submission documents/ Protocol Deviation/Violation Evaluation Form 試驗偏離/背離審查意見表 Protocol Deviation/Violation Review Form 試驗偏離/背離審查意見回覆表 Form of Response to Reviewers' Comments on Protocol Deviation/Violation 會議紀錄 Meeting Minutes

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5.2 試驗偏離/背離案通報

5.2 Protocol Deviation/Violation Reporting

5.2.1 本會人員或執行試驗之相關人員發現可能有試驗偏離/背離情形獲知日起三十天內需通報本會。

5.2.1 IRB personnel or personnel involved in a trial should report to the IRB any potential incident of protocol deviation/violation within 30 days after the discovery of the incident.

5.2.2 承辦人員或執行試驗相關人員填寫「試驗偏離/背離紀錄表」，由執行秘書進行初步評估以決定進一步處置事宜。

5.2.2 IRB staff or personnel involved in a trial should fill in the “Protocol Deviation/Violation Report Form” and submit it to the Executive Secretary for initial assessment and determination on actions needed to be taken.

5.3 通報案件之確認及受理

5.3 Confirmation of Submissions

承辦人員確認「試驗偏離/背離紀錄表」相關資訊填寫無誤後，受理通報。

IRB staff should confirm that the information filled in on the “Protocol Deviation/Violation Report Form” is complete and accurate before processing the report.

5.4 遴選審查委員

5.4 Selection of Reviewers

承辦人員將完整之「送審文件」送（副）主任委員圈選一或二名委員審查，委員之選擇以該計畫原來負責初審之委員為優先，如遇特殊狀況得重新圈選委員審查。

IRB staff should submit the complete submission documents to the (Vice) Chair. The (Vice) Chair should assign one or two reviewers, preferably the original reviewers of the protocol. Under special circumstances, new reviewers may be assigned.

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5.5 委員審查

5.5 Review

委員應依照「試驗計畫書」內容進行審查，確定試驗之執行均符合應有程序。

The reviewer should conduct the review according to the approved protocol to ensure that the implementation of the trial complies with required procedures.

5.5.1 委員審查通報事件，依事件情節判定為輕微/嚴重/持續性不遵從。必要時，可請主持人提供更詳細資訊。審查建議得為「建議修正或提供進一步說明」、「提大會請委員討論」或「於大會核備後存查」。

5.5.1 When reviewing the notified incident IRB members shall determine the severity of the incident as Minor/Serious /Continuing Non-compliance based on the circumstance. If necessary, the IRB shall ask the principal investigator to provide further details. The IRB members shall recommend one of the following suggestions: "recommended for revision or provided further explanation", "sent to the full board for discussion" or "submit to full board for confirmation".

5.5.2 若委員認定為輕微，委員將審查是否需要有改善措施。若有，將建議或請主持人提出改善措施，並於回覆後送原審委員複審是否同意，審查結果存查，排入大會進行核備；若不同意則建議再提會討論。

5.5.2 In the case that an incident has been determined as Minor Non-compliance, the IRB members shall determine whether improvement measures are needed. If yes, the principal investigator shall be asked to respond in writing with improvement measures, and the reply shall be sent to the original reviewers for review and approval. The results of the review shall be recorded in the IRB board meeting documents and passed to the IRB board meeting for verification. In the case that the reviewers are not satisfied with the reply of the principal investigator, the

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case will be passed to the next IRB board meeting for discussion.

5.5.3 若委員判定屬嚴重或持續性不遵從，則需提大會討論。

5.5.3 If the case is determined to be Serious or Continuing Non-compliance by the IRB members , it needs to be discussed in the IRB board meeting.

5.6 計畫主持人回覆

5.6 The PI's Response to Reviewers' Comments

5.6.1 當審查委員有意見時，承辦人員應隱去審查者姓名並將意見內容以電子檔交給計畫主持人，請其回覆。計畫主持人補件（回覆審查意見）天數為 7 個日曆天；若超過 28 個日曆天仍未回覆則逕行撤案。

5.6.1 If the reviewer has comments the staff member should remove the reviewer's name before sending the comments to the PI for response. The comments should be sent in an electronic file. The PI should submit supplementary documents within 7 calendar days. If the PI does not respond within 28 calendar days, the protocol should be withdrawn from IRB consideration.

5.6.2 若審查結果為「於大會核備後存查」，由承辦人員請計畫主持人回覆審查意見或再確認後，於大會進行核備。

5.6.2 If the review decision is "submit to full board for confirmation," the staff member should ask the PI to respond to reviewers' comments and/or reconfirm the review decision before submitting the report to the IRB board meeting for confirmation.

5.6.3 若審查結果為「建議修正或提供進一步說明」，計畫主持人應於限期內回覆審查意見及檢送更正附件，再將主持人之回覆意見轉請審查委員再次評核。

5.6.3 If the review decision is "recommended for revision or provided further explanation," then the PI should respond to the reviewers' comments and submit relevant revised documents. The response and supplementary

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documents from the PI should be sent to the reviewers for evaluation.

5.6.4 若審查結果為「提大會請委員討論」，計畫主持人應於限期內回覆審查意見，承辦人員彙整資料後排入最近一次大會議程討論。

5.6.4 If the review decision is “submit to the full board for discussion,” then the PI should respond to the reviewers’ comments by the due date. The staff member should compile relevant documents and place the report on the agenda for the next scheduled IRB meeting for discussion.

5.7 大會討論/核備

5.7 IRB Board Meeting Discussion/Confirmation

5.7.1 承辦人員必須將所有之試驗偏離/背離事件列入大會議程，並將計畫偏離/背離的詳細情況提大會討論/核備。

5.7.1 The staff member should place all reports of protocol deviation/violation incidents on the agenda for the IRB board meeting and submit details of each incident to the IRB full board for discussion/confirmation.

5.7.2 主任委員和出席委員必須於大會上充分討論，必要時請該計畫主持人列席說明，並將會議決議以書面通知計畫主持人。

5.7.2 The Chair and all attending members should thoroughly discuss the reports during the board meeting. If necessary, the PI may be invited to give a presentation in the meeting. The PI should be notified by writing the resolution from the IRB board meeting.

5.7.3 大會決議及後續處置通知計畫主持人，後續處置依情節輕重包含以下方式：

5.7.3 The PI should be notified of the resolution from the IRB board meeting and actions to be taken. Actions to be taken may include the following, depending on the severity of the incident:

5.7.3.1 輕微不遵從之處置方式

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5.7.3.1 "Minor Non-compliance" management method

5.7.3.1.1 大會核備。

5.7.3.1.1 The incident should be sent to the IRB full board for recordation.

5.7.3.1.2 研究相關人員接受教育訓練。

5.7.3.1.2 Research personnel should receive training.

5.7.3.1.3 實地訪查。

5.7.3.1.3 A monitoring visit should be conducted.

5.7.3.1.4 其他(如：請贊助廠商/CRO 提出改善計畫或訓練證明)。

5.7.3.1.4 Other: (e.g. requiring the sponsoring company/CRO to submit an improvement plan or relevant training certificates).

5.7.3.2 嚴重/持續性不遵從之處置方式

5.7.3.2 "Serious/Continuing Non-Compliance" management method

5.7.3.2.1 研究相關人員接受教育訓練。

5.7.3.2.1 Research personnel should receive training.

5.7.3.2.2 實地訪查。

5.7.3.2.2 A monitoring visit should be conducted.

5.7.3.2.3 暫停或終止該計畫進行。

5.7.3.2.3 The protocol should be suspended or terminated.

5.7.3.2.4 不受理計畫主持人申請新案。

5.7.3.2.4 New protocol submissions from the PI will not be accepted.

5.7.3.2.5 其他：

5.7.3.2.5 Other:

5.7.3.2.5.a 當有可能影響受試者繼續參與研究意願的資訊

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時，需通知已加入研究的受試者。

5.7.3.2.5.a Subjects participating in the research study should be advised in the event of new information that might affect the subject's willingness to continue participating in the research study.

5.7.3.2.5.b 提供曾參與研究的受試者額外的資訊。

5.7.3.2.5.b Provide additional information to subjects already participating in the study.

5.7.3.2.5.c 修訂計畫書。

5.7.3.2.5.c Revised protocol.

5.7.3.2.5.d 修改追蹤審查報告之追蹤頻率。

5.7.3.2.5.d Changing the tracking frequency of the continuing review report.

5.7.3.2.5.e 修訂受試者同意書，並重新取得正在參與試驗的受試者再同意。

5.7.3.2.5.e Revising the subject inform consent form and re-obtaining the subjects inform consent.

5.7.3.2.5.f 監測受試者知情同意過程。

5.7.3.2.5.f Monitoring the process of obtaining informed consent from subjects.

5.7.3.2.5.g 請贊助廠商/CRO 提出改善計畫或訓練證明。

5.7.3.2.5.g Requiring the sponsoring company/CRO to submit an improvement plan or relevant training certificates。

5.7.3.2.5.h 其他

5.7.3.2.5.h Other

5.7.4 若計畫案所發生的試驗偏離/背離事件，符合人體研究法第 17 條第二、三款之規範時，需將審查結果通知衛生福利部，並通知本院受試者保護中心。

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5.7.4 In the case that test deviation/violation incident has occurred which complies with the specifications of the second and third items of Article 17 of “Human Subjects Research Act”, the Ministry of Health and Welfare the Human Research Protection Center at this hospital shall be notified of the results of the IRB review.

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	試驗偏離/背離紀錄表 Protocol Deviation/Violation Report Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
2	試驗偏離/背離評估表 Protocol Deviation/Violation Evaluation Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
3	試驗偏離/背離審查意見表 Protocol Deviation/Violation Review Form	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
4	試驗偏離/背離審查意見回覆表 Form of Response to Reviewers’ Comments on Protocol Deviation/Violation	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. Appendices

「試驗偏離/背離審查意見表」為線上系統輸入，無版本誤用之虞，故不列入附件管理。

“Protocol Deviation/Violation Review Form” is generated from the online system, preventing the usage of the wrong version; therefore, this item is not listed in the appendices.

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6.1 試驗偏離/背離紀錄表

6.1 Protocol Deviation/Violation Report Form

6.2 試驗偏離/背離評估表

6.2 Protocol Deviation/Violation Evaluation Form

6.3 試驗偏離/背離審查意見回覆表

6.3 Form of Response to Reviewers' Comments on Protocol Deviation/Violation

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