**試驗偏差及不遵從計畫自我檢核表**

Protocol Violation/Deviation/Non-Compliance Self-Check List

|  |  |  |  |
| --- | --- | --- | --- |
| IRB編號IRB-TPEVGH No. |  | 通報序號Notification number | 第\_\_\_\_\_\_\_\_\_\_次 |
| * 計畫主持人/試驗委託者發現試驗計畫未依照本委員會審查通過之計畫書執行或未遵循國內/國際人體試驗相關法規時，須於計畫主持人得知日起15個工作日內主動填寫通報試驗偏差及不遵從計畫通報表向本委員會通報。Where identifying any protocol deviation from approved protocols or any noncompliance with domestic/international human trial regulations, the principal investigator or sponsor shall fill out a Notification of protocol Violation/Deviation/Non-Compliance voluntarily within 15 working days from the date when PI knows and report to IRB.
 |
| 1. 試驗偏差程度（定義請參考下方說明）：

[ ]  **輕微不遵從(minor noncompliance)：**雖有違規情形(人體研究及試驗之執行偏離所核准之計畫書內容或相關規範)，但不至於增加受試者或研究對象原先預估之風險。例如：* + - * 未通知人體試驗委員會而有研究團隊成員之異動
			* 縮短返診追蹤的間距
			* 未事先獲得委員會之核准而小幅更改問卷內容

[ ]  **重大不遵從( serious noncompliance)：**違規的結果增加受試者危險、影響受試者權益，或是可能損及研究的正確性。例如：* + - * 未事先獲得委員會核准即進行介入性研究
			* 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
			* 未依計畫進行知情同意過程，對於新藥、新醫療技術、新醫療器材等人體研究及試驗過程的監督不周全
			* 未能遵守委員會為保障受試者安全而給予的建議
			* 未依規定向委員會通報不良事件、意外狀況、計畫案之變更等
			* 嚴重偏離計畫書內容以致增加受試者參加試驗之風險。
 |
| 1. 是否為撤銷或勘誤過去已通報之偏離案

[ ] 否[ ] 是[ ] 撤銷先前試驗偏差(**請填過去已通報之偏離案通報序號：** )通報，理由：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_The reason for the withdrawal of the previously reported experimental deviation.[ ] 勘誤先前試驗偏差(**請填過去已通報之偏離案通報序號：** )通報內容，說明：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_The correction of the previously reported experimental deviation. |
| 1. 所通報問題/事件結果(可複選)Outcome of the problem/event(check all that apply)

[ ] 受試(檢、訪)者並未因所通報問題/事件受不良影響Participant was not adversely affected by the problem/event[ ] 危及生命Resulted in life threatening[ ] 延長住院Resulted in prolonged hospitalization[ ] 暫時失能Resulted in permanent disability[ ] 自動復原Resolved spontaneously[ ] 經處理或治療後復原Resolved with treatment[ ] 停止提供受試(檢、訪)者研究介入Participant discontinued study intervention[ ] 受試(檢、訪)者退出研究Participant withdraw from the study[ ] 死亡，請提供造成死亡之詳細說明及文件Participant died, if checked, please provide a detailed description of the circumstances that led to the death[ ] 其他，請述明Other, please specify：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. 本次試驗偏差的主因Main causes of experimental deviation：

（請於下方勾選合適之選項Please check the appropriate options below，）* **與計畫主持人/研究團隊相關Relevant to the principal investigator/research team**

[ ] 未通知人體試驗委員會而有研究團隊成員之異動Changes in research team members without notifying the Human Research Ethics Committee[ ] 未事先獲得核准即進行研究/試驗Conducting research/experiments without prior approval[ ] 計畫書未將應檢測項目列入Failing to include required testing items in the protocol[ ] 未依計畫進行知情同意過程或簽署同意書Not following the informed consent process or obtaining consent forms as per the protocol[ ] 收案條件不熟悉，將應排除之受試者收案Not being familiar with the enrollment criteria, leading to the inclusion of subjects who should have been excluded[ ] 不熟悉檢驗流程，執行錯誤流程程序Lack of familiarity with the testing procedures, resulting in errors in the process[ ] 遺漏應檢查項目Omitting required checks[ ] 考慮病人病情及健康狀況，而未遵從計畫書流程Not adhering to the protocol process due to considerations of the patient's condition and health status[ ] 檢體不當處理、研究檢體/資料不當保存Improper handling of specimens, improper storage of research specimens/data[ ] 使用尚未送審之文件Using documents that have not been submitted for review[ ] 因系統未即時更新，導致未能同步文件版本Failure to synchronize document versions due to the system not being updated in real-time[ ] 未即時通報SAE (Serious Adverse Events) Failure to report SAE in a timely manner[ ] 其他，請述明Other, please specify：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* **與受試者相關 Relevant to the subject**

[ ] 受試者未回診或回診超出許可期限The subject did not return for follow-up or returned after the allowed deadline[ ] 服藥不確實、未歸還藥瓶Inconsistent medication adherence, failure to return the medication bottle[ ] 未按時填寫紀錄、紀錄不確實、漏填問卷Failure to fill in records on time, inaccurate records, or missing questionnaires[ ] 病情惡化造成無法完成檢驗流程Deterioration of the condition preventing the completion of the testing process[ ] 因其他病況而誤服試驗禁藥Taking prohibited trial medications due to other medical conditions[ ] 其他，請述明Other, please specify：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* **與其他因素相關Related to other factors**

[ ] 其他檢驗單位疏忽，遺漏檢驗項目或數據Negligence by other testing units, missing testing items or data[ ] 注射藥物儀器異常Abnormalities in the injection device[ ] 其他照護單位疏忽，誤刪檢查項目Negligence by other care units, mistakenly deleting testing items[ ] 物流無法運送檢體Logistics unable to transport specimens[ ] 其他，請述明Other, please specify：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |