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-2014 IRB-Regulations of Operation-2014	文件名稱 Title	藥品不良反應(ADR)、嚴重不良事件(SAE)或非預期問題(UP)的監測管理程序書 SOP for Adverse Drug Reaction, Serious Adverse Event or Unanticipated Problem Monitoring
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，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	6	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 SOP 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.新增 5.2.2.4 若計畫主持人超過通報期限之相關程序。 2. Added the procedure for late SAE submissions from principal investigators in item 5.2.2.4.	20160318
D	4	1.修改參考文件 3.1 及 5.5.2 藥品優良臨床試驗準則版本。 1. Revised the version of Regulations for Good Clinical Practice in Reference 3.1 and item 5.5.2. 2.修改 5.3.2 遴選非藥品試驗計畫之審查委員之權責：刪除（副）主任委員。 2. Revised item 5.3.2 regarding the personnel responsible for selecting reviewers for non-drug-related protocols: Deleted "(Vice) Chair." 3.抽換附件 6.3 臨床試驗未預期嚴重藥品不良反應審查表。 3. Replaced Appendix 6.3 Suspected Unexpected Serious Adverse Reaction Review Form.	20170709
E	16	1.依據 FERCAP 國際訪視之建議，新增參考文件 3.2「The Council for International Organizations of Medical Sciences (CIOMS), International ethical guidelines for health-related research involving humans, 2016」。 1. Added Reference 3.2 "The Council for International Organizations of Medical Sciences (CIOMS), International ethical guidelines for health-related research involving humans, 2016." in conformity with suggestions made by FERCAP after their visit.	20190527

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E	16	2.新增參考文件 3.3「嚴重藥物不良反應通報辦法」。 2. Added Reference 3.3 “Regulation of Reporting Serious Adverse Reaction of Medical Products.” 3.新增非預期問題（Unanticipated Problems, UP）之相關敘述。 3. Added statements about Unanticipated Problems (UP). 4.原 5.2「SAE 通報申請」修改為「SAE/UP 通報申請」，並重新編排各項內容順序。 4. Changed item 5.2 “SAE Reporting Application” to “SAE/UP Reporting Application” and rearranged the order of all contents. 5.新增 5.2.1.3：醫療器材/醫療技術之臨床試驗遵照衛生主管機關所公告之「嚴重藥物不良反應通報辦法」辦理。其他非屬人體試驗或臨床試驗之人體研究，其不同類型之嚴重不良反應或安全性通報亦可適用本程序。 5. Added Item 5.2.1.3: The clinical trials of Medical Device/Medical Technology follow the “Regulation of Reporting Serious Adverse Reaction of Medical Products” issued by the government health authorities. This rule also applies to reports of various SAEs and safety notifications of other human studies that are not clinical trials. 6.新增 5.2.2 UP(unanticipated problem)通報：執行任何類型計畫所發生非預期問題(UP)，須通報本院，計畫主持人應於獲知日起 7 日內通報本會，15 日內提供詳細資料。 6. Added Item 5.2.2 Unanticipated Problem (UP) reporting: it is required that the IRB Committees be informed of UPs of all studies. The principal investigator should send preliminary documents on UPs within 7 days from the first day knowing the events and provide more detailed documents within 15 days.	20190527

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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
E	16	7.重新編排 5.6 大會討論/核備之各項內容順序。 7. Rearranged the order of item 5.6 IRB Board Meeting/Approval and Confirmation. 8.新增 5.6.2.1 同意核備。 8. Added item 5.6.2.1 Approval and confirmation. 9.新增 5.7 計畫主持人所檢送之定期安全性報告，其內容若不涉及 SUSAR，請以「其他事項」方式進行通報。 9. Added item 5.7 If SUSAR is not involved, the regular safety report by the PI should be submitted in the category of “Other Items.” 10.修改附件 6.1、6.2、6.3。 10. Modified Appendices 6.1, 6.2, 6.3. 11.新增附件 6.4、6.5。 11. Added Appendices 6.4, 6.5.	20190527
F	17	1. 修改「藥品優良臨床試驗準則」中文名稱為「藥品優良臨床試驗作業準則」。 1. Revised the Chinese name of "Regulations for Good Clinical Practice". 2. 刪除 5.2.1.3 之「醫療器材」項目。 2. The “Medical Device” was deleted in item 5.2.1.3. 3. 新增 5.2.1.4：醫療器材之臨床試驗遵照衛生主管機關所公告之「醫療器材管理法」辦理。 3. Added Item 5.2.1.4: The clinical trials of Medical Device follow the “Medical Devices Act” issued by the government health authorities.	20210528

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F	17	4. 文字校正。 4. Typos were fixed.	20210528
G	17	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. 依據 AAHRPP 國際認證之建議新增 5.6.2.5。 3. According to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) was added Items 5.6.2.5. 4. 原標號 5.6.2.5 修改為 5.6.2.6。 4. Changed item numbers 5.6.2.5 to 5.6.2.6. 5. 抽換附件 6.1 ~ 6.5。 5. Appendices 6.1-6.5 were replaced.	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。

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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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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.	

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.目的

1. Purpose

1.1 本管理程序書之目的在於提供任何經核准的試驗在進行時所發生的藥品不良反應（Adverse Drug Reaction, ADR）、嚴重不良事件（Serious Adverse Event, SAE）或非預期問題（Unanticipated Problems, UP）於通報和審查時之指引。

1.1 The purpose of this SOP is to provide instructions on reporting and reviewing adverse drug reactions (ADRs), serious adverse events (SAEs) or unanticipated problems (UPs) arising from any approved trials.

1.2 試驗過程中可能發生未預期性的風險，對受試者之權益、福祉或安全會有不良影響，此時應確實通報，且人體研究倫理審查委員會應檢視審查，以保護受試者。

1.2 Unanticipated risks may emerge in the course of a trial and have an adverse effect on the subject's rights, welfare or safety. In the event of this, all information must be reported to the IRB for assessing and reviewing to ensure protection of subjects.

2.適用範圍

2. Scope

2.1 依據 99 年 7 月 19 日「藥品優良臨床試驗作業準則」(原名稱為「藥品優良臨床試驗準則」)第 106 條修正條文，受試者發生任何嚴重不良事件，試驗主持人應立即通知試驗委託者，若此 SAE 屬於未預期之嚴重藥品不良反應（Suspected Unexpected Serious Adverse Reaction, SUSAR)，試驗主持人應立即通知本會。

2.1 According to Article 106 of the "Regulations for Good Clinical Practice", amended on 19 July 2010, the principal investigator shall immediately report any serious adverse events to the sponsor. In the event of a suspected unexpected serious adverse reaction (SUSAR), the principal investigator shall

report to the IRB immediately.

2.2 本管理程序書適用於由計畫主持人、獨立數據監測委員會、試驗委託者、人體研究倫理審查委員會委員或其他相關團體所提報本會之未預期嚴重不良反應/事件或非預期問題報告之檢視及審查。

2.2 This SOP is applicable to the principal investigator, the Independent Data Monitoring Committee, the sponsor, the IRB and other relevant groups for the assessment and review of any and all unexpected serious adverse reactions/events or unanticipated problems that are reported by them.

3.參考文件

3. References

3.1「藥品優良臨床試驗作業準則」(原名稱為「藥品優良臨床試驗準則」)第一百零六條修正條文(民國 103 年 10 月 23 日衛生福利部部授食字第 1031203335 號令修正發布)

3.1 Regulations for Good Clinical Practice, Article 106 (Ministry of Health and Welfare, amended and promulgated on 23 October 2014, pursuant to Bu-Shou-Shi-Zi No. 1031203335).

3.2 The Council for International Organizations of Medical Sciences (CIOMS), International ethical guidelines for health-related research involving humans, 2016.

3.3「嚴重藥物不良反應通報辦法」。民國 93 年 08 月 31 日行政院衛生署衛署藥字第 0930324850 號令訂定發布。

3.3 Regulation of Reporting Serious Adverse Reaction of Medical Products (Ministry of Health and Welfare, promulgated on 31 August 2014, pursuant to Wei-Shou-Yao-Zi No. 0930324850).

4.名詞定義

4. Definitions

4.1 不良事件(Adverse Event, AE):受試者參加試驗後所發生之任何不良情況,此項不良情況不一定與治療有因果關係。

4.1 Adverse Event (AE): Any untoward medical occurrence in a trial subject during participation in the trial, which does not necessarily have a causal relationship with the trial intervention.

4.2 嚴重不良事件(Serious Adverse Event, SAE):因試驗致發生下列嚴重不良反應者:

4.2 Serious Adverse Event (SAE): Any serious adverse reaction that occurs during a trial which results in any of the following outcomes:

4.2.1 死亡(Death):如病患死亡被認為係不良反應之直接結果。

4.2.1 Death: If the patient's death is suspected as being a direct outcome of the adverse reaction.

4.2.2 危及生命(Life-threatening):如病患於發生不良事件時有死亡危險,或如繼續使用試驗產品可能造成病患死亡。例如:心臟節律器功能喪失;胃腸道出血;骨髓功能抑制;輸液幫浦功能異常造成藥物劑量過量等。

4.2.2 A life-threatening event: If the patient is at risk of death at the time of the adverse event or it is suspected that the continued use of the trial product would result in the patient's death. Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure that results in excessive medicine dosing.

4.2.3 導致病人住院或延長病人住院時間(Hospitalization)—如因不良事件發生導致病患需住院或延長住院時間。例如:過敏性反應;偽膜性結腸炎;出血導致住院或延長住院時間等。

4.2.3 Inpatient hospitalization or prolongation of existing hospitalization: If admission to the hospital or prolongation of a hospital stay is because of the suspected adverse event. Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging the existing hospitalization.

4.2.4 永久性殘疾(Disability/Incapacity):如不良事件對病患身體

功能/結構、身體活動或生命品質，造成嚴重性、永久性的改變、損害或傷害。例如：因藥物引起過度凝集之腦血管意外；中毒；周邊神經病變等。

4.2.4 A significant or persistent disability/incapacity: If the adverse event results in a significant or persistent change, impairment, or damage in the patient's body function/structure, physical activities, or quality of life. Examples: Cerebrovascular accident due to medicine-induced hypercoagulability; toxicity; peripheral neuropathy.

4.2.5 先天性畸形（Congenital anomaly / Birth defect）：如於懷孕前或懷孕期間暴露於藥品導致胎嬰兒不良結果等。

4.2.5 A congenital anomaly or birth defect: For example, exposure to a drug prior to conception or during pregnancy results in an adverse outcome in the child.

4.2.6 其他可能導致永久性傷害需作處置者（Others）：懷疑因使用藥品造成需要內科或外科介入治療以防止病患永久性失能或傷害等。

4.2.6 Other events that may lead to permanent damage: When there is suspicion that the drug used in the trial causes persistent/permanent impairment or damage of a patient and leads to necessary medical or surgical intervention.

4.3 藥品不良反應（Adverse Drug Reaction, ADR）：使用藥品後所發生之有害且未預期之反應【如未在計畫書（study protocol）/主持人手冊(Investigator's Brochure)/ 藥品仿單(product monograph) / 受試者同意書(Informed Consent Form)等揭示之可能副作用】。此項反應與試驗藥品間，應具有合理之因果關係。

4.3 Adverse Drug Reaction (ADR): A response, which is noxious and unintended, that occurs after the administration of pharmaceuticals and is considered to have a causal relationship with the trial drug. For example: A potential side-effect that is not listed in the study protocol, Investigator's Brochure, product monograph and/or the Informed Consent

Form.

4.4 未預期之嚴重藥品不良反應（Suspected Unexpected Serious Adverse Reaction, SUSAR）：為高度懷疑、非預期的嚴重藥品不良反應。

4.4 Suspected Unexpected Serious Adverse Reaction (SUSAR): A serious adverse reaction that is unexpected and is highly suspected to be related to a trial drug.

4.5 非預期問題（Unanticipated Problems, UP）：指發生非預期、與研究程序或試驗用藥相關或可能相關、並產生更嚴重的傷害之問題或事件。包括：

4.5 Unanticipated Problems (UP): A problem or event that occurs unexpectedly, is related to, or may be associated with a research protocol or trial medication that produces unexpected serious harm which could include the following:

4.5.1 本院受試者所發生涉及新的風險或風險增高且與研究相關的非預期事件或問題。

4.5.1 Subjects in our hospital are involved in new risks or risks that are unanticipated or unexpected associated with the study.

4.5.2 院外受試者所發生對受試者或其他人造成風險且與研究相關的非預期不良事件或問題。

4.5.2 Unexpected adverse events or problems that incur to subjects outside the host institute or other persons associated with the study.

4.5.3 為了避免立即且明顯的危害，於本會核准變更前先行進行的變更。

4.5.3 To avoid immediate and obvious hazards, changes to the research protocol made prior to the approval by the IRB Committees.

4.5.4 其他有關研究可能對受試者或其他人增加傷害風險的非預期資訊。

4.5.4 Other relevant new research and information concerning unexpected increased risks or injuries to the subjects or other persons.

4.5.5 可能影響受試者安全或臨床試驗執行有不利影響之新資訊。

4.5.5 New information that may affect the subject's safety or lead to adverse effects related to execution of the study.

4.5.6 任何顯著影響臨床試驗執行或增加受試者風險的任何改變。

4.5.6 Any change that markedly affects the execution of the study or increases subject risks.

4.5.7 違反保密協定之情事。

4.5.7 Violation of the confidentiality agreement.

4.5.8 試驗/研究案中之藥物、醫療器材，或其他醫用相關物品發生如許可證更動或許可證取消等之情事。

4.5.8 Drugs, medical devices, or other medical-related items in the study case that may be subject to license change or license cancellation.

4.5.9 當受試者在納入研究後成為受刑人，主持人得知後應通報研究倫理委員會及試驗委託者。

4.5.9 When a recruited subject becomes a prisoner after the start of the study, the principal investigator should promptly inform the IRB Committees and the sponsor.

4.5.10 當受試者進行申訴或抱怨，且此申訴或抱怨內容屬非預期之風險性或試驗/研究團隊無法解決此事件。

4.5.10 In the case when a subject complains outside the anticipated risks, and the complaints cannot be resolved by the research team.

4.5.11 試驗委託者/廠商具停止牌照之風險。

4.5.11 The sponsor or manufacturer has the risk of license cancellation.

4.5.12 發生具需要立即通報試驗委託者/廠商之情事。

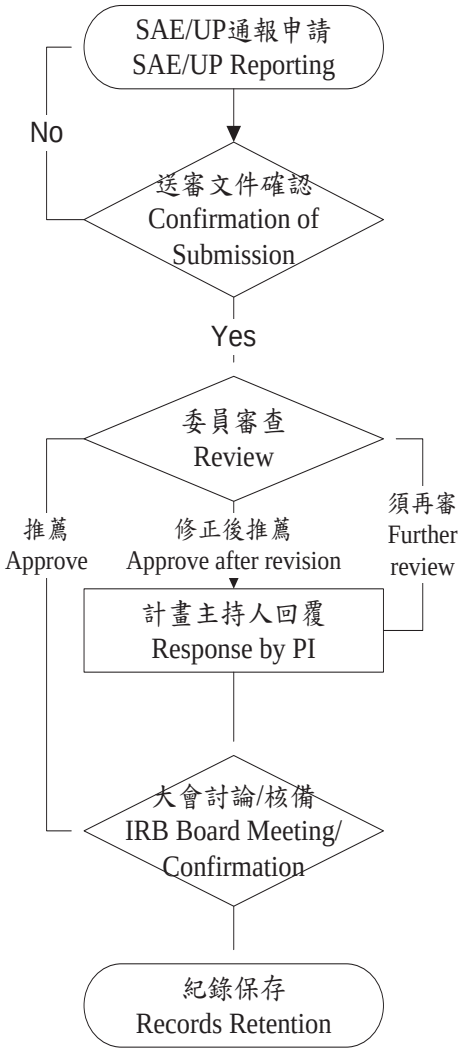
4.5.12 In cases when events occur that require immediate notification of the sponsor or manufacturer.

5.作業內容

5. Procedure

5.1 嚴重不良事件及非預期問題監測與評估管理流程圖

5.1 Flow Chart of Serious Adverse Event (SAE) and Unanticipated Problem (UP) Monitoring and Management

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	計畫主持人 Principal Investigator 承辦人員 Staff Members 審查委員 Reviewers 計畫主持人 Principal Investigator 委員 IRB Members 承辦人員 Staff Members	臨床試驗嚴重不良事件/非預期問題通報相關表格 SAE/UP Report Form and relevant documents 臨床試驗嚴重不良事件(僅通報 SUSAR)/非預期問題通報表 SAE (only SUSAR is reported)/UP Report Form 臨床試驗嚴重不良事件(僅通報 SUSAR)/非預期問題審查表（審查委員） SAE (only SUSAR is reported)/UP Review Form (for reviewers) 臨床試驗嚴重不良事件(僅通報 SUSAR)/非預期問題審查表（審查委員） SAE (only SUSAR is reported)/UP Review Form (for reviewers) 臨床試驗嚴重不良事件(僅通報 SUSAR)/非預期問題審查表（審查委員） SAE(only SUSAR is reported)/UP Review Form (for reviewers)

5.2 SAE/UP 通報申請

5.2 SAE/UP Reporting

5.2.1 SAE 通報

5.2.1 SAE Reporting

5.2.1.1 計畫主持人有義務將執行中計畫所發生的發生未預期之嚴重藥品不良反應填表並通報人體研究倫理審查委員會。

5.2.1.1 The principal investigator is accountable for documenting and reporting any serious drug reaction arising from the trial to the IRB.

5.2.1.2 通報時效(依據 103 年 10 月 23 日「藥品優良臨床試驗作業準則」第 106 條修正條文辦理):

5.2.1.2 Reporting time limit (followed in accordance with Article 106 of Regulations for Good Clinical Practice, amended on 23 October 2014):

5.2.1.2.1 受試者發生任何嚴重不良事件(Serious Adverse Event, SAE),試驗主持人應立即通知試驗委託者,並儘快提供詳細書面報告。發生未預期之嚴重藥品不良反應(Suspected Unexpected Serious Adverse Reaction, SUSAR),試驗主持人應立即通知人體研究倫理審查委員會。但若試驗計畫書或其他文件明確排除者,不在此限。

5.2.1.2.1 Upon occurrence of an SAE, the principal investigator is responsible for reporting immediately to the sponsor, promptly followed by the submission of a detailed report. The principal investigator is to notify the IRB immediately of all SUSARs. However, SAEs/SUSARs that the protocol or other document identifies as not needing immediate reporting shall not apply.

5.2.1.2.2 試驗委託者獲知未預期之死亡或危及生命之嚴重藥

品不良反應，應於獲知日起七日內通報主管機關或其委託機構，並在獲知日起十五日內提供詳細書面資料。

5.2.1.2.2 The sponsor shall report all SUSARs that are fatal or life-threatening to the competent authority or the sponsoring agency within 7 days of discovery of the event. A detailed report is to be submitted within 15 days after the discovery of the event.

5.2.1.2.3 試驗委託者獲知未預期之死亡或危及生命以外之嚴重藥品不良反應，應於獲知日起十五日內通報主管機關或其委託機構，並提供詳細書面資料。

5.2.1.2.3 SUSARs that are not fatal or life-threatening must be reported, via written documentation, to the competent authority or the sponsoring agency no later than 15 days after the sponsor was notified of the event.

5.2.1.2.4 若計畫主持人超過通報期限（7 日及 15 日）方進行通報，本會秘書處將會提至大會進行討論，並依大會決議辦理（如：實地訪查等）。

5.2.1.2.4 If the PI reports a SUSAR later than the reporting time limit (7 days and 15 days after the occurrence of the event), the IRB Secretariat should place the report on an IRB board meeting agenda for discussion. Follow-up actions may be taken according to the IRB board meeting resolution (e.g. an on-site inspection).

5.2.1.3 醫療技術之臨床試驗遵照衛生主管機關所公告之「嚴重藥物不良反應通報辦法」辦理。其他非屬人體試驗或臨床試驗之人體研究，其不同類型之嚴重不良反應或安全性通報亦可適用本程序。

5.2.1.3 The clinical trials of Medical Technology follow the “Regulation of Reporting Serious Adverse Reaction of Medical Products” issued by the government health

authorities. This rule also applies to report of various SAEs and safety notification of other human studies that are not clinical trials.

5.2.1.4 醫療器材之臨床試驗遵照衛生主管機關所公告之「醫療器材管理法」辦理。

5.2.1.4 The clinical trials of Medical Device follow the “Medical Devices Act” issued by the government health authorities.

5.2.2 UP(unanticipated problem)通報

執行任何類型計畫所發生非預期問題(UP)，須通報本院，計畫主持人應於獲知日起 7 日內通報本會，15 日內提供詳細資料。

5.2.2 Unanticipated Problem (UP) Reporting:

UPs of all studies are required to notify the IRB Committees. The principal investigator should send preliminary documents on UPs within 7 days from the first day knowing the events and provide more detailed documents within 15 days.

5.3 送審文件確認

5.3 Confirmation of Submission

5.3.1 承辦人員確認「臨床試驗嚴重不良事件(僅通報 SUSAR)/非預期問題通報表」相關資訊填寫無誤後，受理申請。

5.3.1 Once the SAE (only SUSAR is reported)/UP Report Form is verified as complete by the IRB staff, the submission will be processed for review.

5.3.2 承辦人員接獲通報後，若為藥品相關試驗計畫，將送請具藥學/藥理背景委員進行審查。其他則陳報執行秘書遴選相關委員審查。

5.3.2 Upon receipt of a complete submission, the IRB staff member should submit drug-related protocols to reviewers with expertise in pharmacy/pharmacology. Other protocols should be submitted to reviewers with relevant expertise

as assigned by the Executive Secretary.

5.4 委員審查

5.4 Review

5.4.1 負責初步審查之委員將評估 SUSARs/UP 是否確為未知、罕見或須委員會採取進一步處理以維護受試者安全者，並填寫「臨床試驗嚴重不良事件(僅通報 SUSAR)/非預期問題審查表（審查委員）」。

5.4.1 The primary reviewers are responsible for: (1) classifying the Suspected Unexpected Serious Adverse Reaction /Unanticipated Problems as unexpected, rare or requiring further action by the IRB to ensure subject safety; (2) completing the SAE (only SUSAR is reported)/UP Review Form (for Reviewers).

5.4.2 若經委員審查判定為不影響受試者的風險，則提大會核備。

5.4.2 If the reviewers determine that the event does not present a risk that may affect trial subjects, the report should be submitted to the IRB board meeting for confirmation.

5.4.3 若多中心之試驗計畫於本院發生之未預期嚴重藥品不良反應或非預期問題，經判定為「極有可能相關」或「確定相關」者，得通報國內其他人體研究倫理審查委員會。

5.4.3 In case of a SUSAR or UP encountered in a multi-center trial, if the causality of assessment by the reviewers is “probable” or “related,” other domestic IRBs should be notified of the event report.

5.5 計畫主持人回覆

5.5. PI’s Response to Reviewers’ Comments

審查委員若有意見之計畫，承辦人員應隱去審查者姓名之意見內容影印交計畫主持人，請其回覆。

A copy of the reviewers’ comments, if applicable, should be sent to the principal investigator by the IRB staff members, with the reviewers’ names removed. The principal investigator should be requested to respond to the reviewers’ comments.

5.6 大會討論/核備

5.6 IRB Board Meeting/Confirmation

5.6.1 承辦人員將審查完成之「臨床試驗嚴重不良事件(僅通報SUSAR)/非預期問題審查表(審查委員)」呈送執行秘書/(副)主任委員批示。分二方式處理：

5.6.1 The IRB staff members are responsible for submitting the SAE (only SUSAR is reported)/UP Review Form (for reviewers) to the Executive Secretary/(Vice) Chair for approval, following one of the two procedures:

5.6.1.1 若此事件可能導致受試者風險提高，則召開緊急會議討論。

5.6.1.1 If the event presents higher risk to the subjects, an emergency meeting should be convened.

5.6.1.2 若此事件不影響受試者風險，則將審查結果提至下次大會討論/核備。必要時邀請主持人蒞會報告或提供資料。承辦人員依大會討論決議執行或將資料存檔備查。

5.6.1.2 If the event does not affect the risk level that the trial presents to the subjects, then the review result should be placed on the agenda for the next IRB meeting for discussion/confirmation. The PI may be invited to present or provide documentation in the IRB meeting. The staff members should follow up according to the IRB meeting resolution or retain relevant files for future reference.

5.6.1.3 若此通報事件經大會出席委員充分討論與審查後，認為確實可能增加受試者的風險，應於會議上做成決議，請主持人提出說明，或於會後進行對該案的追蹤審查或實地訪查、或決議暫停或終止試驗，以維護受試者安全。

5.6.1.3 If the IRB members—after discussing and reviewing the report in a convened IRB meeting—determine that the event probably posed an increased risk to

the subjects, then one of the following resolutions should be made: (1) The principal investigator should be requested to provide further explanation; (2) an on-site visit or follow-up review should be conducted; (3) the trial should be suspended or terminated to protect the safety of the subjects.

5.6.2 對受試者風險的影響，決議的處理方式分為：

5.6.2 The IRB may make one of the following resolutions regarding risks presented to the subjects:

5.6.2.1 同意核備。

5.6.2.1 Approving the report for recordation.

5.6.2.2 請主持人提出書面說明。

5.6.2.2 Requesting additional written explanation from the principal investigator.

5.6.2.3 進行對該案的追蹤審查或實地訪查。

5.6.2.3 Conducting a follow-up review or performing an on-site inspection.

5.6.2.4 暫停或終止試驗。

5.6.2.4 Suspending or terminating the trial.

5.6.2.5 當此類資訊可能與受試者繼續參與研究的意願有關時，將通知受試者。

5.6.2.5 Notification of current subjects when such information might relate to subjects' willingness to continue to take part in the research.

5.6.2.6 其他。

5.6.2.6 Others.

5.6.3 發生在國內其他醫療機構之未預期之嚴重藥品不良反應，承辦人員先將資料鍵入資料庫，並統計每月通報件數，呈送執行秘書/（副）主任委員批示。分二方式處理：

5.6.3 SUSARs that occur in other domestic medical care

institutions shall be entered into the database. This information, along with the total number of reported events, calculated on a monthly basis, shall be submitted to the Executive Secretary/(Vice) Chair, following one of the procedures:

5.6.3.1 若可能增加受試者的風險，則依情況召開緊急會議，或至大會提出討論與審查。

5.6.3.1 If the event presents increased risks to the subjects, then an emergency meeting should be convened, or the report should be submitted to the IRB board meeting for discussion and review.

5.6.3.2 若不影響受試者的風險，則將資料存檔備查。

5.6.3.2 If the event does not affect the level of risks presented to the subjects, then the report may be filed for future reference.

5.6.4 主任委員決定需召開臨時會議時，由承辦人員負責聯絡安排。

5.6.4 If the IRB Chair decides to call an extraordinary meeting, the staff member should be responsible for arranging the meeting.

5.6.5 當院內執行之研究計畫案，受試者發生未預期嚴重藥品不良反應之初始報告或非預期問題件數太多時，本會將就該計畫案進行實地訪查作業。

5.6.5 The IRB should conduct an on-site visit to monitor a TCVGH-affiliated trial in which a significant number of SUSAR initial reports or UP have been filed.

5.6.6 承辦人員依大會決議通知計畫主持人、試驗單位及贊助廠商。

5.6.6 The IRB staff members shall notify the principal investigator, the unit implementing the trial, and the sponsoring agency of the IRB resolution.

5.7 計畫主持人所檢送之定期安全性報告，其內容若不涉及SUSAR，請以「其他事項」方式進行通報。

5.7 If SUSAR is not involved, the regular safety report by the PI

should be submitted in the category of “Other Items.”

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 guideline below.

編號 Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	臨床試驗(院內/本院執行)嚴重不良事件(僅通報 SUSAR)/非預期問題通報摘要表 SAE (only SUSAR is reported)/UP Report Form (Trials within TCVGH)	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
2	臨床試驗(院外/其他試驗機構)嚴重不良事件(僅通報 SUSAR)/非預期問題通報摘要表 SAE (only SUSAR is reported)/UP Report Form (Trials outside of TCVGH)	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
3	臨床試驗嚴重不良事件(僅通報 SUSAR)/非預期問題審查表（審查委員） SAE (only SUSAR is reported)/UP Review Form (for reviewers)	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
4	臨床試驗（院內/本院執行）嚴重不良事件(僅通報 SUSAR)/非預期問題通報回函 Reply Form of a SAE (only SUSAR is reported) /UP Report (Trials within TCVGH)	IRB 檔案室 IRB Archive	試驗結束後 3 年 At least 3 years after the trial is closed
5	臨床試驗（院外/其他試驗機構）嚴重不良事件(僅通報 SUSAR)/非預期問題通報回函 Reply Form of a SAE (only SUSAR is reported) /UP Report (Trials outside of TCVGH)	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

6.1 臨床試驗（院內/本院執行）嚴重不良事件(僅通報SUSAR)/非預期問題通報摘要表

6.1 SAE (only SUSAR is reported)/UP Report Form (Trials within TCVGH)

6.2 臨床試驗（院外/其他試驗機構）嚴重不良事件(僅通報SUSAR)/非預期問題通報摘要表

6.2 SAE (only SUSAR is reported)/UP Report Form (Trials outside of TCVGH)

6.3 臨床試驗嚴重不良事件(僅通報SUSAR)/非預期問題審查表（審查委員）

6.3 SAE (only SUSAR is reported)/UP Review Form (for reviewers)

6.4 臨床試驗（院內/本院執行）嚴重不良事件(僅通報SUSAR)/非預期問題通報回函

6.4 Reply Form of a SAE (only SUSAR is reported)/UP Report (Trials within TCVGH)

6.5 臨床試驗（院外/其他試驗機構）嚴重不良事件(僅通報SUSAR)/非預期問題通報回函

6.5 Reply Form of a SAE (only SUSAR is reported)/UP Report (Trials outside of TCVGH)