1.目的 Purpose

為保障受試者權益，人體試驗審查委員會(以下簡稱人委會)處理研究試驗計畫終止及暫停(中止)時之流程。

To protect the rights of the subjects, the Institutional Review Board (hereinafter referred to as “IRB”) will handle the termination and suspension (discontinuance) processes of the study.

2. 適用範圍 Scope

2.1 研究試驗計畫於預定結束前，因計畫主持人嚴重或持續性違規，或在持續審查、修正/變更審查或稽核過程中發現非預期問題，經審查會討論認定增加受試者風險或造成受試者權益受損，人委會應暫停(中止) 或終止研究/試驗計畫。

For studies that are about to be ended as expected, if the PI are found seriously or continuously violating against regulations, or the IRB has found unexpected problems during continuing review, review for corrections/amendments or audit, and the review meeting has discussed and determined that the previous issue will increase the risks of the subjects or cause damages to the rights of the subjects, the IRB shall suspend (discontinue) or terminate the study/trial protocol.

註：計畫主持人或試驗委託者主動自願終止或暫停案則不適用此範圍，應依「審查計畫結案、終止、撤案報告」及「其他事項處理辦法」作業程序申請。

Note: the studies that the PI or sponsor actively and willingly terminate or suspend are not applicable to this document, which instead shall be applied in

accordance with the "Review for study closure, termination and withdrawal reports" and "Processing Regulations for Other Matters".

3.參考文件 References

3.1 赫爾辛基宣言(Declaration of Helsinki)中文版 (2013 年 10 月)

The Chinese Version of Declaration of Helsinki (October, 2013)

3.2 人體研究倫理審查委員會組織及運作管理辦法 (2012 年 8 月)

Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research (August 2012)

3.3 藥品臨床試驗計畫書主要審核事項 (2004 年 2 月)

The Primary Review Items of the Pharmaceutical Clinical Trial Protocol (February 2004)

3.4 藥品優良臨床試驗準則（2014 年 10 月）

Guidelines of Good Clinical Practice (October 2014)

3.5 WHO Operational Guidelines for Ethics Committees that Review Biomedical Research，WHO 2000

3.6 Forum for Ethical Review Committees in Asia and the Western Pacific，August 2003

3.7 倫理審查委員會得簡易程序審查之人體研究案件範圍 (2012 年 7 月)

The Scope of Human Study for Expedited Review Conducted by the Institutional Review Board (July 2012)

3.8 醫療法 (2014 年 1 月)

Medical Care Act (January 2014)

3.9 人體試驗管理辦法 (2009 年 12 月)

Regulations on Human Trials (December 2009)

3.10 人體研究法 (2011 年 12 月)

Human Subjects Research Act (December 2011)

3.11 得免取得研究對象同意之人體研究案件範圍 (2012 年 7 月)

The Scope of Human Study Granted for Waiver of Subject Consent (July 2012)

3.12 得免倫理審查委員會審查之人體研究案件範圍 (2012 年 7 月)

The Scope of Human Study Granted for Waiver of the Institutional Review Board Review (July 2012)

3.13 AAHRPP 基準 Domain II 2G,Tip Sheet 21 Suspensions and Terminations of IRB or EC Approval, 2016

AAHRPP Baseline Domain II 2G,Tip Sheet 21 Suspensions and Terminations of IRB or EC Approval, 2016

4.名詞定義 Terminology

4.1 暫停(中止)：暫時撤銷人委員會對該計畫之許可，直到問題改善後，並經人委會決定該計畫是否可能重新開始或計畫必須終止。

Suspension (Discontinuance): the IRB will suspend the approval temporarily until it has been improved. The IRB will decide whether the study can resume or has to be terminated.

4.2 終止：人委會自即日起永久撤銷對該計畫之許可。

Termination: the IRB will revoke the approval of the study permanently, which becomes effective from this date.

5.作業內容 Scope of operation

5.1 流程 Process

程序 Procedure	**權責 Rights and responsibilities**	**相關文件 Related documents**
計畫主持人嚴重或持續性違規，或在持續審查、修正/變更審查或稽核過程中發現非預期問題 The PI seriously or continuously violates against regulations, or the IRB uncovers unexpected problems during continuing review, review for corrections/amendments, or audit.	計畫主持人/執行秘書 Principal Investigator/Executive secretary	
審查會議審查，緊急時由主任委員核定暫停並於下次會議討論 The review meeting will review the application. The committee director will review and approve the suspension of the study and move it to the next meeting for discussion when emergency.	審查會議/主任委員 Review meeting/Committee director	
通知計畫主持人，必要時通知衛生主管機關 Notify the PI and notify the health authorities if necessary	主任委員 Committee director	
妥善保存計畫相關文件 Store study-related materials properly	行政秘書 Administrative secretary	

5.2 職責 Responsibilities

5.2.1 主任委員：召開審查會議；緊急時核定計畫案暫停(中止)，並於下次會議討論。必要時通知衛生主管機關。

Committee director: convenes review meetings; approves study suspension (discontinuance) during emergency, and reports such cases to the next meeting for discussion. The health competent authorities will be informed if necessary.

5.2.2 執行秘書：須協助處理計畫終止的流程。

Executive secretary: helps handle the process of study termination.

5.2.3 計畫主持人必須完全停止該計畫之執行。為保護受試者安全，計畫主持人必須妥善處理受試者之後續權益保障。

The principal investigator must completely stop the implementation of the study. To protect the safety of the subject, the PI must handle properly to protect the subsequent rights of the subjects.

5.2.4 行政秘書：妥善保存計畫相關文件。

Administrative secretary: will retain study-related files properly.

5.3 細則 Rules

5.3.1 暫停(中止)計畫

Study Suspension (Discontinuance)

5.3.1.1 經稽核或接獲具名投訴發現計畫主持人嚴重或持續性違規，或因非預期問題增加受試者風險或造成受試者權益受損，由執行秘書蒐集相關資訊，並由計畫主持人提供妥善處理受試者權益保障之書面計畫，呈報委員會。

If it is uncovered that the risks of the subjects have been increased or the rights of the subjects have been violated due to serious or continuous violations made by the PI or unexpected problems

uncovered by audit or receiving named complaints, the executive secretary will collect relevant information and report to the IRB.

5.3.1.2 經審查會討論認定該缺失/風險可改善，人委會對研究計畫之執行進行暫停(中止)計畫之決議，暫停期限由審查會決議。當情況緊急無法待召開會議討論時，主任委員可暫停(中止)計畫， 並提下次會議報告。

If the review meeting believes that the defect/risk could be improved, the IRB will make a decision of suspending (discontinuing) the study, and the period of suspensions will be decided by the IRB. If any emergency situations have met and thus does not allow convening review meetings, the committee director may suspend (discontinue) the study and report the application to next meeting for discussion.

5.3.1.3 計畫主持人須提出缺失/風險改善方案，並確實執行，改善結果提交人委會審議，決議通過後始得恢復計畫執行。

The PI must submit and implement a defect/risk improvement plan, and then submit the improved results to the IRB. The implementation will resume after the resolution has been approved.

5.3.1.4 人委會對於重大缺失得對計畫主持人提出暫停新案申請之處分。

The IRB will propose sanctions (i.e. suspend new applications) against the PI due to significant defects.

5.3.2 終止的決議

The resolution of study termination

5.3.2.1 經稽核或接獲具名投訴發現計畫主持人嚴重或持續性違規，或因非預期問題增加受試者風險或造成受試者權益受損，由執行秘書蒐集相關資訊，並由計畫主持人提供妥善處理受試者權益保障之書面計畫，呈報委員會。

If it is uncovered that the risks of the subjects have been increased or the rights of the subjects have been violated due to serious or continuous violations made by the PI or unexpected problems uncovered by audit or receiving named complaints, the executive secretary will collect relevant information and report to the IRB.

5.3.2.2 經審查會討論認定該缺失/風險嚴重危害受試者權益，人委會對研究計畫之執行進行終止計畫之決議，在討論審查時，須考慮下列事項。

A.對目前參與之受試者採取保護措施，以維護其權利與福

社。

B.對退出之受試者安排醫療處置以維護其權利與福祉 (例如安排適當之醫療照護、轉介給其他研究者等)

C.通知目前參與試驗之受試者此暫停或終止試驗之決定

D.若有任何不良事件或結果須通報人委會。

For the defects/risks which the review meeting believes that they may seriously compromise the rights of the subjects after discussion, the IRB will make a resolution to terminate the implementation of the study. For emergency circumstance that the review meeting does not have sufficient to be convened,

the committee director may suspend (discontinue) the study and report such applications to the next meeting for report.

5.3.2.3 當情況緊急無法待召開會議討論時，主任委員可先暫停(中止)計畫， 並提下次會議報告。

5.3.2.4 人委會決議終止之計畫案，計畫主持人必須完全停止該計畫之執行，並執行受試者後續權益保障之措施。

The PI must completely stop the implementation of the study. In addition, to protect the safety of the subjects, the PI must properly protect the rights of the subjects in the future.

5.3.2.4 人委會對於重大缺失得對計畫主持人提出暫停新案申請之處分。

The IRB may propose sanctions (i.e. suspend new applications) against the PI due to significant defects.

5.3.3 決議結果通知

Notifications of the resolutions

5.3.3.1 IRB 應記錄暫停或終止之決定及原因，並於主任委員簽核後 7 個工作天內，書面通知計畫主持人、受試者保護中心、院長、試驗委託者（若需要）、院外監督該計畫之單位（若需 要）、衛生福利部（若需要）、美國 OHRP（若適用）、美國 FDA（若 適用）。

The IRB shall record the decisions and reasons for study suspension or termination, and inform the PI, Center for Human Subject Protection (CHSP), superintendent, sponsor (if necessary), surveillance units outside of the hospital (if necessary), MOHW (if necessary), US OHRP (if applicable), US FDA (if applicable) in

writing within 7 working days after the committee director has signed and approved the above application.

5.3.3.2 若決議為暫停，計畫主持人應於接獲通知 14 個工作天內提出確保受試者權益保護之措施，並回覆經會議決議須修正事項，再由 IRB 審議後決定是否可恢復執行或終止試驗。

If the resolution is to suspend the study, the PI shall submit an application for study suspension within 14 working days after receiving the notification, describe the measures to protect the rights of the subjects, and respond to the IRB regarding amendments decided by the meeting. The IRB will decide whether the implementation of the study could be resumed or terminated after the review.

5.3.3.3 若決議為終止，計畫主持人應於接獲通知立即執行確保受試者權益保護之措施，並於 14 個工作天內提出執行進度報告，且於 3 個月內繳交結案報告。

If the resolution is to terminate the study, the PI shall submit an application for study termination within 14 working days after receiving the notification, and respond to the IRB regarding measures to protect the rights of the subjects.

5.3.3.4 計畫主持人若未於接獲通知 14 個工作天內執行確保受試者權益保護之措施，人委會再次通報受試者保護中心並暫不受理計畫主持人申請新案。

If the PI fails to submit the application of study termination or

suspension within 14 working days after receiving the notification, the administrative secretary will issue the notification again 1 month after the resolution has been issued. For those who fail to submit applications within 3 months, the PI's new applications will not be received temporarily. For those who fail to submit applications within 6 months, the study shall be terminated directly.

5.3.3 妥善儲存計畫相關檔案

Store study-related files properly

5.3.3.1 暫停或終止研究之所有相關正本文件與計畫書一併歸檔。

All study suspension- or termination-related original files and protocols shall be archived altogether.

6.附件 Attachment

無 NA