1.目的 Purpose

提供人委會處理已核准之計畫案提前中止(暫停)或終止及撤案時的流程與處理依據。

To provide the IRB with process and handling foundations for early discontinuance (suspension) or termination and withdrawal of the approved protocols.

2. 適用範圍 Scope

適用所有試驗委託者、計畫主持人或主管機關建議應予暫停或終止及撤案的研究計畫案。

It is applicable to all study protocols that the Sponsors, Principal Investigators or competent authorities have recommended to suspend or terminate and withdraw.

3.參考文件 References

3.1 藥品優良臨床試驗準則(2015年10月)

Guidelines of Good Clinical Practice (October 2015)

3.2 人體研究法（2011年12月）

Human Subject Research Act (December 2011)

3.3 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

3.4 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996

4.名詞定義 Terminology

4.1 暫停(提前中止)：已核准的研究計畫案，主管機關/機構/試驗委託者/試驗主持人發現試驗執行中有安全疑慮，須進一步評估，得主動或被動

暫時停止執行部分或全部研究計畫。

Suspension (early discontinuance): for approved study protocol, if the competent authorities/institutes/Sponsor/Principal Investigator has uncovered the concerns about safety which requires further evaluation, the entire or partial study thereby shall be actively or passively suspended.

4.2 終止：已核准的研究計畫案，主管機關/機構/試驗委託者/試驗主持人發現試驗執行中有顯著影響受試者權益事件發生(例如：確認療效不佳或安全有疑慮...等)，於計畫完成前得主動或被動結束全部研究計畫，不再進行。

Termination: for approved study protocol, if the competent authorities/institutes/Sponsor/Principal Investigator has uncovered the occurrence of major events that will significantly affect the rights of the subjects during the study (e.g. confirmed poor efficacy or concerns about safety, etc.), the entire study thereby shall be actively or passively terminated before study completion, and the continuance of implementation is prohibited.

4.3 撤案：新申請之研究計畫案在尚未核准前，計畫主持人主動結束研究計畫案申請時，即可提出撤案申請。

Withdrawal: before the application of new study protocol has been approved, the Principal Investigator may apply for study withdrawal while actively finish the application for study protocols.

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
申請撤案或暫停/終止 Apply for withdrawal or suspension/termination	申請人/計畫主持人 Applicant/Principal Investigator	送審清單與相關資料 Checklist of files for submission
受理送審文件 Receive submitted files	行政人員 Administrative staff	送審清單與相關資料 Checklist of files for submission
審查 Review	審查委員/專家 Reviewer/Expert	送審資料 Files for review
審查會議 Review meeting	人委會 IRB	議程與紀錄 Meeting agenda and minutes
會議決議/通知 Meeting resolutions/Notifications	行政人員 Administrative staff	會議紀錄、公文、提前中止決議函 Meeting minutes, official letters, early discontinuance resolution letter
歸檔 Archiving	行政人員 Administrative staff	相關文件 Related documents

5.2 職責 Responsibilities

5.2.1 主任委員：指派委員/專家審查。

Committee director: the person who can appoint IRB members/experts for review.

5.2.2 審查委員/專家：於期限內完成審查，並送回審查意見。

Reviewers/experts: shall complete review procedures and send back the review comments to the administrative staff.

5.2.3 行政人員：受理申請案件、將審查意見彙整至人委會會議審查、將會議決議通知計畫主持人、文件歸檔。

Administrative staff: receive applications, document study protocols, summarize review comments and report to the IRB meeting for further review, notify review results to the Principal Investigator, and archive files.

5.2.4 試驗委託者：應提出撤案或暫停/終止研究計畫案書面報告，通知計畫主持人及主管機關。

Sponsor is the entity to provide written study protocols for withdrawal or suspension/termination and inform the Principal Investigator and competent authorities.

5.2.5 計畫主持人:提出撤案或暫停/終止研究計畫案申請資料。

Principal Investigator: the person to submit application materials for study protocol withdrawal or suspension/termination.

5.3 審查流程 Review process

5.3.1. 申請撤案或暫停/終止:

Apply for withdrawal or suspension/termination:

5.3.1.1 由計畫主持人提出研究計畫案撤案(附件一)或暫停/終止的申請

表(附件二)及暫停或終止個案收案表(附件三)。

The Principal Investigator will submit the Study Protocol Withdrawal Application Form (Attachment 1) or Study Protocol Suspension/Termination Application Form (Attachment 2) or Study Protocol Suspension or Termination Case Report Form (Attachment 3).

5.3.1.2 由主管機關(衛生福利部)/機構(受試者保護中心)，向人委會提出暫停或終止進行中的研究，行政人員依來文直接受理。

The competent authorities (Ministry of Health and Welfare, MOHW)/Institutes (Center for Human Subject Protection, CHSP) will submit suspension or termination to the IRB for ongoing studies. The administrative staff will receive the cases based on the incoming official letters.

5.3.2 受理送審文件：

Receive submitted files:

5.3.2.1 行政人員受理並核對暫停/終止研究計畫案申請資料，確認申請文件齊全後，由主任委員指派委員/專家審查。

The administrative staff will receive and verify the application materials for study protocol suspension/termination. The committee director will appoint reviewers/experts for case review after the administrative staff has confirmed all required materials are well prepared.

5.3.2.2 行政人員受理主管機關(衛生福利部)/機構(受試者保護中心)向人委會提出暫停/終止進行中的研究，請計畫主持人準備相關資料，

排入審查會議或召開緊急會議討論。召開緊急會議依標準作業程序（SOP 2.13）規定辦理。

The administrative staff will receive the applications submitted by the competent authorities (MOHW)/Institutes (CHSP) to the IRB for study suspension/termination, ask the Principal Investigator to prepare relevant materials, and schedule into the IRB meeting for emergency discussion. The convening of emergency meeting will be in accordance with SOP 2.13.

5.3.2.3 撤案申請，行政人員確認申請文件齊全後，逕行撤案並入會備查。

To apply for study withdrawal, the administrative staff will verify whether all the required files are well-prepared and then withdraw the application directly, and report to the IRB meeting for reference.

5.3.3 審查委員/專家審查

Review conducted by the reviewers/experts

5.3.3.1 審查委員須於 5 個工作日內完成計畫暫停或終止審查意見表(附件四。若委員發現遺漏審查資料，則應告知行政人員。

The reviewers must complete the protocol Suspension or Termination Review Comment Form (Attachment 4) within 5 working days. If the reviewer has uncovered any missing materials for review, he/she shall inform the administrative staff.

5.3.3.2 審查重點:Review focuses

A. 受試者權利與福祉之保護措施。

The protection measures regarding subject’s rights and welfare.

B. 後續之醫療照護安排。

The arrangement of subsequent medical care.

C. 受試者是否轉介給其他研究者。

Have the subjects been transferred to other researchers.

D. 如何將研究終止之訊息通知受試者。

How to inform the subjects about the information of study termination.

E. 發生不良事件/未預期事件，需通報人委會

The occurrence of adverse event (AE)/unanticipated problems (UP) that requires to inform the IRB.

5.3.3.3 審查委員/專家需勾選同意存查、修正後提會討論、召開緊急會議

The reviewers/experts are required to select the item that they agree to materials retention for reference, material resubmission after amendment and the calling for emergency meeting.

5.3.4 審查會議審議結果得為下列之決定：

The review results of the review meeting will be as follows:

A. 【核准】：同意撤案存查/立即暫停/立即終止研究計畫案。

[Approved]: Agree to withdrawal for retention and reference/suspension immediately/terminate immediately for the study protocol.

B. 【核准，需增加受試者保護措施】：計畫主持人須立即暫停/終止研究計畫案，且須於 2 週內提受試者權利與福祉之保護措施，或申請變更案。

[Approved, but subject protection measures are needed]: The

Principal Investigator must suspend/terminate the study protocol immediately and propose protection measures for subject's rights and welfare within 2 weeks, or apply for amendments.

5.3.5 審查結果於會議後 7 個工作日內通知計畫主持人。緊急會議決議須於會議後 1 個工作日內通知計畫主持人。

The review results will be informed to the Principal Investigator within 7 working days after the meeting. The review results from the emergency meeting shall be informed to the Principal Investigator within 1 working day after the meeting.

5.3.6 計畫主持人不依會議決議執行時，人委會得暫停計畫主持人申請新案，直到完成會議決議止。

If the Principal Investigator fails to comply with the meeting resolutions, the IRB has rights to suspend the Principal Investigator from applying for new studies until the Principal Investigator has completed all meeting resolutions.

5.3.7 計畫主持人欲申請解除計畫暫停時，填寫解除計畫暫停申請表(附件六)後送審，審查流程依標準作業程序（SOP 2.7）規定辦理。

For Principal Investigator who intends to apply for study suspension, he/she shall fill in Study Protocol Suspension Application Form (Attachment 6). The review process shall be in accordance with SOP 2.7.

5.3.8 文件歸檔依標準作業程序（SOP 6.1）規定辦理。

File archiving shall be processed in accordance with SOP 6.1.

6.附件

6. Attachment

6.1 附件一 (KMUH/IRB/AF/2.10-01/11.0) 撤案申請表

Attachment 1 (KMUH/IRB/AF/2.10-01/11.0) Study Protocol Withdrawal Application Form

6.2 附件二 (KMUH/IRB/AF/2.10-02/11.0) 研究計畫案暫停/終止申請表

Attachment 2 (KMUH/IRB/AF/2.10-02/11.0) Study Protocol Suspension/Termination Application Form

6.3 附件三 (KMUH/IRB/AF/2.10-03/11.0) 暫停或終止個案收案表

Attachment 3 (KMUH/IRB/AF/2.10-03/11.0) Study Protocol Suspension or Termination Case Report Form

6.4 附件四 (KMUH/IRB/AF/2.10-04/11.0) 撤案/計畫暫停/終止審查意見表

Attachment 4 (KMUH/IRB/AF/2.10-04/11.0) Withdrawal/Suspension/Termination Review Comment Form

6.5 附件五 (KMUH/IRB/AF/2.10-05/11.0) 撤案/計畫暫停/終止決議函

Attachment 5 (KMUH/IRB/AF/2.10-05/11.0) Withdrawal/Suspension/Termination Resolution Letter

6.6 附件六 (KMUH/IRB/AF/2.10-06/11.0) 解除計畫暫停申請表

Attachment 6 (KMUH/IRB/AF/2.10-06/11.0) Study Protocol Suspension Application Form