1.目的 Purpose

提供人委會已通過計畫案之結案報告審查事宜。

To provide the final report review matters that have been approved by the IRB.

2.適用範圍 Scope

適用人委會通過的所有研究計畫案。

It is applicable to all IRB-approved study protocols.

3.參考文件 References

3.1 藥品優良臨床試驗準則 (2014 年 10 月)

Guidelines of Good Clinical Practice (October 2014)

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) June 1996.

4.名詞定義 Terminology

4.1 結案報告：試驗完成或提早終止時，試驗主持人及試驗機構提供試驗委託者、人委會及主管機關之報告。

Final report: refers to the report that the Principal Invetigator and trial institute will provide the Sponsor, IRB and competent authorities when the study has completed or early terminated.

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
送交申請資料 Submit the application	申請人/計畫主持人 Applicant/Principal Investigator	依送審資料清單 Checklist of files for review
確認送審文件內容 Verify submitted files	行政人員 Administrative staff	依送審資料清單 Checklist of files for review
審查 Review	原初審委員 Original reviewers	送審資料 Files for review
審查會議 Review Meeting	人委會 IRB	會議議程/紀錄 Meeting agenda/minutes
製作核准文件 Prepare approved files 歸檔 Archiving	行政人員 Administrative staff	公文 Official letter

5.2.職責 Responsibilities

5.2.1 主任委員：指派審查委員/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:於期限內完成審查程序,並將審查意見送回行政人員。

Reviewers/experts: Completes 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；彙整初審審查意見至人委會會議審查；審查決議通知計畫主持人；文件歸檔。

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

5.2.4 申請人/計畫主持人應於研究核准迄日後 3 個月內提出結案報告。

The applicant/Principal Invetigator shall submit the final report within 3 months after the study has been ended.

5.3 細則 Rules

5.3.1 行政人員於研究核准迄日前通知繳交結案報告 (附件一)

The Administrative staff shall inform about Final Report Submission (Attachment 1) before the approved last date of the study.

5.3.1.1 第一次通知：核准迄日前 30 個日曆天。

The 1st notification: 30 calendar days before the approved last date of the study.

5.3.1.2 第二次通知：核准迄日當天。

The 2nd notification: The approved last date of the study.

5.3.1.3 第三次通知：核准迄日算起，後 30 個日曆天。

The 3rd notification: 30 calendar days after the approved last date of the study.

5.3.1.4 第四次通知：核准迄日算起，後 60 個日曆天。

The 4th notification: 60 calendar days after the approved last date of the study.

5.3.1.5 第五次通知：自核准迄日算起，後 90 個日曆天。提會討論，相關處置如下

The 5th notification: 90 calendar days after the approved last date of the study. For reporting to the meeting for discussion, relevant handling processes are as follows:

A.繳交結案報告前，人委會不受理計畫主持人申請新案。

Before submitting the final report, the IRB will not receive any new applications from the Principal Investigator.

B.特殊原因(如主持人在國外)得予寬限期，計畫主持人務必在寬限期內繳交，否則人委會不受理申請新案。

For special reasons (e.g. the Principal Investigator has gone abroad), the deadline for final report submission could be extended. The Principal Investigator must submit the final report before the deadline of the extension, or the IRB will not receive any new applications.

5.3.2 計畫主持人依規定填寫結案申請資料，包括結案報告送審文件清單、結案報告表（附件二）、結案個案收案表（附件三）、受試者同意書稽核表（附件四）。

The Principal Investigator shall fill in the application materials for final report, including the checklist of final report submission, Final Report Form (Attachment 2), Case Close Case Report Form (Attachment 3).

5.3.3 行政人員於 7 個工作日內核對受試者同意書簽名頁影本(最後一次期中報告繳交後至結案期間)

The Administrative staff shall verify the copies of subject ICF signature pages within 7 working days (the period between the last submission of interim report and the final report)

5.3.3.1 收案人數 30 人以下，請檢附全部受試者同意書簽名頁影本。

For studies with subject sample size less than 30 persons, please attach all subject ICF signature pages based on subject numbers.

5.3.3.2 收案人數 30 人以上，請依受試者編號，以等距抽樣 30 份受試者同意書簽名頁影本。

For studies with subject sample size above 30 persons, please sample 30 copies of subject ICF signature pages isometrically based on subject numbers.

5.3.3.3 正本由主持人自行保管，人委會及主管機關得隨時調閱。

The Principal Investigator shall self-retain the original files for the IRB and competent authorities to review at any time.

5.3.4 委員審查結案報告

Reviewer final report

5.3.4.1 工作人員將結案報告送交原初審委員審查，委員依結案報告審查意見表(附件五)審查，期限為 5 個工作日。委員因故無法審查時，主任委員得另外指派審查委員審查。若執行秘書為醫療委員，主任委員得授權執行秘書分派案件。

The staffs will send the final report to the original reviewers for review. The reviewers shall review the report based on the Final Report Review Comment Form (Attachment 4), and the time frame is 5 working days. If the reviewer fails to review due to certain reasons, the comittee director may appoint other reviewers to review. If the executive secretary is the medical member, the comittee director may authorize the executive secretary to assign the case.

5.3.4.2 審查重點：

Review items:

A.結案報告內容

Final Report Contents

B.受試者同意書簽名頁影本

Copy of subject ICF signature page

5.3.4.3 委員填寫審查意見表時，須勾選【核准】、【修正後複審】、【提會討論】。

When the reviewers are filling the review comment form, they may select [approved], [secondary review after amendment] or [submit to the board meeting for discussion].

5.3.5 審查會議決議

Resolutions of review meeting

5.3.5.1 行政人員彙整委員審查意見表，排入就近日期審查會議審議。

The Administrative staff will summarize the review comment forms and schedule into recent review meeting for review.

5.3.5.2 會議審議結果得為下列之決定：

The review meeting may make one of the following decisions:

A.【存查】：存查的結案報告應於審查會議核備。行政人員以結案報告審查決議通知 (附件六)通知申請人/ 計畫主持人，並製作人體試驗/研究結案報告同意證明書(附件七)，送交主任委員簽核，行政人員應於會議結束後 10 個工作日內，將同意證明書掃描後 E-Mail 給申請人/ 計畫主持人，正本由行政人員歸檔存查。查驗登記用臨床試驗計畫案之結案報告審查通過後，人委會須函送一份結案報告至衛福部審核。

[Retention for reference]: The retained final reports shall be

reported to the review meeting for reference. The Administrative staff will notify the applicant/Principal Investigator using the Final Report Resolution Form (Attachment 6), prepare the Certificate of Approval for Human Trial/Study Final Report (Attachment 7), and then submit to the comittee director for signature and approval. The administrative staff shall scan the certificate of approval and E-Mail to the applicant/Principal Investigator within 10 working days after the meeting. The original files will be retained and archived by the administrative staff for reference. Once the review of the final report of the clinical trial for registration has been approved, the IRB shall issue a final report to Ministry of Health and Welfare for review.

B.【修正後複審】：行政人員以結案報告審查決議通知 (附件六) 通知申請人/ 計畫主持人，申請人/計畫主持人就結案報告審查意見表修正後，依標準作業程序 (SOP 2.7)進行複審。

[Secondary review after amendment]: The Administrative staff will notify the applicant/Principal Investigator using the Final Report Resolution Notification Form (Attachment 6). The applicant/Principal Investigator may amend the application based n the review comment form and submit the amend files for secondary review in accordance with SOP 2.7.

5.3.5.3 若未於審查結果通知日起 14 個日曆天內繳交修正後複審之結案報告，人委會得拒絕計畫主持人申請新案，直到繳交複審文件為止。

If the Principal Investigator fails to submit the amended final report for secondary review within 14 calendar days after the date of notification, the IRB has the right to refuse new applications from the PRINCIPAL INVESTIGATOR until the Principal Investigator has submitted the files for secondary review.

5.3.6 文件歸檔：依標準作業程序（SOP 6.1）進行。

File archiving: shall be in accordance with SOP 6.1.

6.附件 Attachment

6.1 附件一(KMUH/IRB/AF/2.11-01/11.0) 結案報告繳交通知單

Attachment 1 (KMUH/IRB/AF/2.11-01/11.0) Final Report Submission Note

6.2 附件二(KMUH/IRB/AF/2.11-02/11.0) 結案報告表

Attachment 2 (KMUH/IRB/AF/2.11-02/11.0) Final Report Form

6.3 附件三(KMUH/IRB/AF/2.11-03/11.0) 結案個案收案表

Attachment 3 (KMUH/IRB/AF/2.11-03/11.0) Case Close Case Report Form

6.4 附件四(KMUH/IRB/AF/2.11-04/11.0) 受試者同意書稽核表

Attachment 4 (KMUH/IRB/AF/2.11-04/11.0) Subjecy ICF Audition Form

6.5 附件五(KMUH/IRB/AF/2.11-05/11.0) 結案報告審查意見表

Attachment 5 (KMUH/IRB/AF/2.11-05/11.0) Final Report Review Comment Form

6.6 附件六(KMUH/IRB/AF/2.11-06/11.0) 結案報告審查決議通知

Attachment 6 (KMUH/IRB/AF/2.11-06/11.0) Final Report Review Resolution Notificat