修訂紀錄

版本	修訂日期	公告日期	執行日期	修訂原因
11.1	2018/1/19	2018/2/15	2018/3/1	1.依AAHRPP STEP 1建議修訂
11.2	2018/4/27	2018/5/15	2018/6/1	1.依AAHRPP STEP 1建議修訂
11.3	2018/7/27	2018/8/15	2018/9/1	1.每年定期更新。 2.依據現況修訂。 3.修訂「初審審查意見表」
11.4	2018/8/30	2018/9/15	2018/10/1	依AAHRPP修訂
11.5	2018/10/26	2018/11/1	2018/12/1	依AAHRPP評鑑意見建議修訂

1. 目的 Purpose
   提供人委會受理初次申請人體研究審查之程序及管理的依據。
   To provide IRB with a dependable reference for the procedure and management of first-time applications for IRB review.
2. 適用範圍 Scope
   初次申請簡易審查或一般審查的計畫案。
   This SOP shall apply to projects applying for initial expedited review or full board review.
3. 參考文件 References
   3.1. 藥品優良臨床試驗準則(2015年10月)
   Regulations for Good Clinical Practice (Oct 2015)
   3.2. 新醫療技術（含新醫療技術合併新醫療器材）(2002年10月)
   New Medical Technology (including new medical technology with new medical devices) (Oct 2002)
   3.3. 人體試驗計畫作業規範(2002年10月)
   Human Trial Operational Regulations (Oct 2002)
   3.4. 醫療器材查驗登記審查準則(2014年)
   Regulation for Registration of Medical Devices (2014)
   3.5. 醫療器材管理辦法(2015年)
   Regulations for Governing the Management of Medical Device (2015)
   3.6. 人體研究法(2011年12月)
   Human Subjects Research Act (Dec 2011)
   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
   Scope of Human Subject Cases for Expedited Review by Institutional Review Board (2012)
   3.8. 人體研究倫理審查委員會組織及運作管理辦法2012
   Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research (2012)
   3.9. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

3.10. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
FDA: 21 CFR 812
AAHRPP Domain II .2.2.D

4. 名詞定義 Terminology

4.1. 人體研究：指從事取得、調查、分析、運用人體檢體或個人之生物行為、生理、心理、遺傳、醫學等有關資訊之研究。
Human Subject Research: Refers to research involving obtaining, investigating, analyzing, or using human specimens or an individual person's biological behavior, physiological, psychological, genetic or medical information.

4.2. 人體檢體：指人體（包括胎兒及屍體）之器官、組織、細胞、體液或經實驗操作產生之衍生物質。
Human Specimens: Refers to human (including a fetus and corpse) organs, tissues, cells, body fluids, or any derivative biomaterial arising from experimentation therewith.

4.3. 簡易審查：適用於審查微小風險的計畫案，符合「醫療機構審查會得簡易審查案件範圍」。
Expedited Review applies to reviewing projects with minimal risk and conforming with the Scope of Cases Available for Expedited Reviews by the Institutional Review Board.

4.4. 最小風險：對身體或心理上造成的傷害的機會或程度，相當於健康受試者的日常生活、常規醫學及心理學檢查所造成者，並沒有因為參與試驗而增加。
Minimal Risk means the chance or degree of physical or psychological harms caused by the trial equals the harms caused to healthy subjects by daily life, conventional medicine, and psychological tests, and no additional risk is caused by the trial.

4.5. 第一期臨床試驗(phase I)：以了解藥物毒性為目的之安全性研究，對象為健康志願者。指研發階段新藥用於人體試驗，測試人體藥物代謝或藥物動力作用，或研究劑量增加所導致的副作用。
Phase I: refers to the safety study on the toxicity of a drug on healthy volunteers. It refers to the test of the metabolism and pharmacokinetics of a new drug through human trials at the development stage or the test of the side effects of a new drug at different doses.

4.6. 第二期臨床試驗(phase II)：以了解藥物療效為目的之初步療效觀察， 對象為病人。人體試驗藥物代謝、結構活動力的關聯或動力機制或應用研發新藥來探究生物現象或疾病進程。
Phase II: refers to the preliminary observation of a drug's pharmacodynamics on patients. It refers to the study of the association between the metabolism and structural activity or the pharmacokinetic mechanism or application of a drug through human trials to investigate biological phenomena or disease progresses.

4.7. 第三期臨床試驗(phase III)：以確認療效及安全性為目的之完整療效評估，對象為病人及對照組， 尚未通過主管機關審核者為Phase IIIa；已通過主管機關審核者為Phase IIIb。採「實驗組—對照組」方式驗證藥效，以獲取更多用藥安全的資訊，供醫師臨床使用參考。
Phase III: refers to the complete pharmacodynamics assessment of a new drug to validate its effectiveness and safety on patients and the control group. Phase IIIa means that the phase has not been approved by competent authorities, while Phase IIIb means that the phase has been approved by competent authorities. In this phase, the pharmacodynamics of a new drug is validated by means of a contrastive study using an "experimental group and a control group" in order to collect more drug safety information for the reference of clinical use.

4.8. 第四期臨床試驗(phase IV)：藥物上市後的安全性監視，對藥物是否產生不良反應，進行長期的追蹤

Phase IV: refers to the post-market safety surveillance of a drug to find out if there are adverse drug reactions (ADR) through long-term tracking.

4.9. 試驗藥品：臨床試驗中用來試驗之藥品，或當做參考之活性成分製劑或安慰劑。包括已上市藥品使用於與其核准內容不同之用途、配方、包裝、適應症、或用於獲得有關核准用途之進一步資料。
Investigational New Drug (IND): refers to a drug used in clinical trials or active principle preparation or placebo for reference use. IND includes marketed drugs used in applications, formulas, packing, and indications different from their approved contents, or used for obtaining the further information of the approved applications.

4.10. 醫療器材：包括診斷、治療、減輕或直接預防人類疾病，或足以影響人類身體結構及機能之儀器、器械、用具及其附件、配件、零件。
Medical Device: includes instruments, equipment, tools and their accessories, fittings, and parts for diagnosis, treatment, relieving or directly preventing human diseases or that can affect human body structure or functions.

4.11. 人體研究參與者/受試者：接受研究人員進行研究的個人，研究內容包括對該個人進行調查、分析、檢驗、治療或其他介入性措施或互動，從中獲取數據或可辨識之個人資料。
Human Research subject: refers to an individual accepting research conducted by investigators, with research contents including the investigation, analysis, examination, treatment, or other interventions or interactions of that individual in order to obtain data or identifiable personal data.

4.12. 受試者同意書：受試者被告知將參與之臨床試驗之相關訊息，且在了解參與試驗之目的、方法、風險及保障後，所簽署表達自願參與試驗之文件。
Informed Consent Form (ICF): a document signed by subjects to express their voluntary participation in a trial, with information relating to the clinical trials they will attend, including the purpose, methodology, risk, and protection of the trial.

4.13. 試驗機構：執行臨床試驗之醫療機構。
Institution: refers the medical institution carrying out the clinical trial.

4.14. 試驗主持人：試驗機構執行臨床試驗之負責人。
Principal Investigator: refers to the responsible person implementing the clinical trial of an institution.

4.15. 試驗委託者：臨床試驗之發起及管理者。
Sponsor: refers to the initiator and administrator of the clinical trial.

4.16. 試驗計畫書：記載臨床試驗之目的、設計、方法、統計考量與編制等事項之文件，並得載明試驗之相關背景及理論。
Protocol: refers to the document that records the purpose, design, methodology, statistical considerations, and staffing of a clinical trial and contains the related background and theories of the trial.

4.17. 主持人手冊：有關試驗藥品之臨床及非臨床數據之編輯物。
Investigator's Brochure: refers to an edited document containing the clinical and non-clinical data of IND.

4.18資深審查委員：參與人委會計畫審查達半年以上之審查委員。

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
新案申請 New project application	申請人/計畫主持人 Applicant/Principal Investigator	申請表 Application form
行政審查 Administrative review	行政人員 Administrative staff	送審文件清單 Files for review
主委/執秘分案 Case assignment of IRB committee director/Executive secretary	主任委員/執行秘書 committee director/Executive secretary	分案通知單 Case assignment notification form
委員審查 Member review	審查委員/專家 Reviewer/Expert	審查意見表 Review comments form
審查會 Review meeting	審查會議 Review Meeting	會議議程 Meeting agenda
結果通知 Outcomes notification	行政人員 Administrative staff	會議記錄 Meetng minutes
歸檔 Archiving	行政人員 Administrative staff	無 NA

5.2. 職責
Duty

5.2.1. 行政人員：受理、核對申請案件資料，並負責將審查意見彙整通知申請人/計畫主持人，文件歸檔。
Administrative Staff: Accept a protocol and check its data; gather review results; notify applicants/principal investigators of the review results; and filing.

5.2.2. 主任委員：負責判定計畫案是否符合案件審查標準。若符合一般案審查標準，則進行分案並指定審查委員。
Committee Director: Determine if a protocol complies with the review criteria. For protocols meeting the criteria of a full board review, assign the protocol and designate appraisers.

5.2.3. 執行秘書：負責判定計畫案件是否符合簡易審查適用範圍，並分派案件及指定資深審查委員進行審查。
Executive Secretary: Determine if a protocol falls within the scope of an expedited review and assign the protocol and designate appraisers.

5.2.4. 審查委員/專家：負責審核計畫案是否符合受試者權益保護，被指定的審查委員/專家應於

期限內完成審查程序，並將審查意見送交行政人員。
Appraiser/Expert: Appraise if a protocol meets the requirements for subject rights and benefits protection. Designated reviewers/experts shall complete the review by the designated deadline and hand over the review results to the administrative staff.

5.2.5. 委員會委員：決議計畫案是否符合受試者權益保護。
Committee Member: Resolve if a protocol meets the requirements for subject rights and benefits protection.

5.3. 試驗案審查流程
Trial protocol review process

5.3.1. 新案申請：申請人/計畫主持人至PTMS申請系統填寫初審案申請表(附件 一)。
New Application: An applicant/principal investigator shall fill in the Initial Review Application Form (Attachment 1) on the PTMS application system.

5.3.1.1. 若屬於藥品/疫苗之研究，須另填寫試驗藥品/疫苗簡介資料表(附件 一.1)。
For IND/vaccine studies, applicants/principal investigators shall also fill in the IND/Vaccine Datasheet (Attachment 1.1).

5.3.1.2. 若屬於醫療器材之研究，須另填寫醫療器材或醫療器材合併新醫療技術簡介資料表(附件 一.2)。
For medical device studies, applicants/principal investigators shall also fill in the Medical Device or Medical Device with New Medical Technology Datasheet (Attachment 1.2).

5.3.1.3. 若屬於醫療技術之研究，須另填寫醫療技術簡介資料表(附件一.3)。
For new medical technology studies, applicants/principal investigators shall also fill in the Medical Technology Datasheet (Attachment 1.3).

5.3.2. 若屬追認案，申請人/計畫主持人依國衛院/ JIRB / C-IRB/NRPB 送審文件清單申請。
For ratification cases, applicants/principal investigators shall submit the list of submittals as requested by the National Health Research Institutes (NHRI), Joint Institutional Review Board (JIRB), the IRB of the Ministry of Health and Welfare (C-IRB), and the National Research Program for Biopharmaceuticals (NRPB).

5.3.2.1. JIRB、NHRI-IRB、C-IRB、NRPB及其他簽訂合作之 IRB 核准的所有文件(PDF 檔)。
JIRB, NHRI-IRB, C-IRB, and NRPB and other cooperation documents (PDF) approved by IRB.

5.3.2.2. 受試者同意書、請另檢附 word 檔(.doc)。
ICF with a separate MS Word (.doc) file.

5.3.2.3. 受試者同意書修正前後對照表。
A cross reference of ICF before and after amendments by subjects.

5.3.2.4. 修正後受試者同意書：本院受試者同意書 (修正內容須有醒目標示)。
Amended ICF: KMUH ICF (amendments shall be highlighted).

5.3.2.5. 修正前受試者同意書：追認委員會核准之受試者同意書。
Original ICF: ICF approved by the Ratification Board.

5.3.2.6. 追認委員會之審查意見(需有回覆內容)。
Review results of the Ratification Board (with reply contents).

5.3.2.7. 追認委員會之核准函。
The approval letter of the of the Ratification Board.

5.3.3. 最小風險的計畫案，得申請簡易審查，申請人/計畫主持人須填寫簡易審查範圍查檢表(附件二)。

Expedited review shall apply to protocols with minimal risks. Applicants/principal investigators shall fill in the Expedited Review Scope Checklist (Attachment 2).

5.3.4. 申請案件須檢附送審文件清單。
Applicants/principal investigators shall submit the list of submittals for all protocols.

5.3.5. 行政審查
Administrative review

5.3.5.1. 行政人員依據送審文件清單核對送審文件。
Administrative staff shall check the submittals with the list of submittals.

5.3.5.2. 確認計畫相關人員GCP受訓時數符合規定，並完成繳費後，於審查會議22個工作日前，確認送審文件無誤後，送至人委會。
Administrative staff shall also verify if the GPC training length of project-related personnel complies with the requirements. After paying the fee and confirming that there is error in the submittals, administrative staff shall deliver the submittals to IRB within 22 workdays before the review meeting.

5.3.5.3. 計畫主持人可至人委會網站下載送審文件以做參考。一般審查送審文件如下：
A principal investigator may download submittals from the IRB website for reference. Submittals of a full board review include:

A. 人體試驗送審文件清單
List of Submittals for Human Trial

B. 新案申請表(附件一)
Initial Review Application Form (Attachment 1)

C. 本院人體試驗切結書(適用於無試驗委 託者之人體試驗案，乙份正本) (非機構內者免)
Declaration of KMUH Human Trial (apply to human trials without a sponsor, one (1) original copy) (exempted for non-institutional trials).

D. 人體試驗之中英文計畫摘要
Chinese and English abstracts of the human trial protocol.

E. 主持人、共同/協同主持人學經歷、著作及GCP/醫學倫理相關證明（申請藥品臨床試驗計畫者，須檢附三年內共計至少9小時GCP及醫學倫理相關證明）。另主持人資格符合醫療法第八條之臨床試驗計畫案請依照行政院衛生福利部規定，其餘請依照本院規定時數標準辦理
The education background, publications, and certificates of GCP/Medical Ethics training (applications for IND clinical trials shall submit certificates of GCP and medical ethics training for a minimum of nine (9) hours over the past three (3) years) of the principal investigator, sub-investigator, and co-investigator. In addition, the qualification for conducting a human trial as specified in Article 8 of the Medical Care Act shall be subject to related requirements of the Ministry of Health and Welfare (MOHW) of the Executive Yuan. Others shall be subject to the training length required by KMUH.

F. 人體試驗計畫書
Human trial protocol.
G. 受試者同意書/基因相關研究受試者同意書
ICF or ICF of subjects for genetic research.
H. 人體試驗繳費收據影本
The photocopy of the receipt of human trial payment.
I. 案例報告書
Case report.
J. 前臨床試驗參考資料
Pre-clinical trial references.
K. 出產國及核准上市國最高主管衛生機關許可製售證明影印本
The photocopy of permits for manufacture and sale issued by the country of origin and the top health authority approving the marketing of a drug.
L. 如尚屬研究中之新藥，應說明其現況並檢附生產國及其他國核准進行臨床試驗之證明文件影印本
For new drugs under development, please specify their status and submit the photocopy of the permit for clinical trail issued by other countries.
M. 臨床研究人員利益衝突宣告揭露聲明書(附件三)
Declaration of Conflict of Interest of Clinical Investigators (Attachment 3).
N. 稽核切結書
Declaration of Audit.
O. 資料及安全性監測計劃（Data and Safety Monitoring Plan，DSMP）(附件四)
Data and Safety Monitoring Plan (DSMP) (Attachment 4)
P. 藥商執照影本
The photocopy of the pharmacist selling license and pharmacist manufacturing license.
Q. 病患日誌卡、禁用藥物卡(若有則請附上)

5.3.5.4. 簡易審查送審文件如下：
Submittals for an expedited review include:
A. 簡易審查計畫案送審文件清單
List of Submittals for Expedited Review
B. 簡易審查計畫案計畫書
Protocol for expedited review
C. 新案申請表(附件一)
D. 計畫主持人、共同主持人、協同主持人個人資料表（CV）
The curriculum vitae of the principal director, sub-investigator, and co-investigator.
E. 計畫主持人、共同主持人、協同主持人3年內人體試驗相關教育訓練課程(IRB/GCP/CITI…)證明文件
Certificates of training (IRB/GCP/CITI…) relating to human trials over the past three (3) years of the principal director, sub-investigator, and co-investigator.
F. 繳費收據影本
The photocopy of the payment receipt.
G. 受試者同意書

ICF

H. 問卷（適用有問卷之研究）
Questionnaire (apply to studies with a survey).

I. 委託護理部檢體收集申請條（適用有委託護理部收集檢體之研究）
Application for sample collection by the nursing department (apply to studies requiring sample collection through the nursing department).

J. 檢體去連結證明文件（適用去連結檢體之研究）
Certificate of sample delinkage (apply to studies using delinked samples).

K. 招募廣告（適用有招募廣告之研究）
Recruitment advertisements (apply to studies with subject recruitment advertisements).

5.3.5.5. 檢體之採集與使用須依衛生福利部最新公告規定辦理。
Samples shall be collected and used with respect to the latest MOHW announcements.

5.3.5.6. 若送審文件未齊全，於 送審文件清單填寫尚缺文件部份，並通知申請人/計畫主持人。
Administrative staff shall list non-submitted documents in the list of missing documents and notify the applicant/principal investigator.

5.3.5.7. 行政人員確認送審相關文件完備後，確認收案。
After confirming the integrity of submittals, administrative staff shall confirm application acceptance.

5.3.6. 主委/執行秘書分案
Case assignment by IRB chairperson/executive secretary

5.3.6.1. 執行秘書依人體研究相關法規之規範，判定送審案件是否為人體研究，不屬於人體研究者，以書面通知申請人/計畫主持人判定結果。
The executive secretary shall determine if the protocol is a human subject research based on the regulations governing human subject research and notify the applicant/principal investigator of the outcomes.

5.3.6.2. 執行秘書依照以下標準判定是否符合簡易審查案件：
The executive secretary shall determine if study meets the requirements for an expedited review with respect to the following criteria:

A. 非新醫療技術、新藥品、新醫療器材、學名藥生體可用率、生體相等性、或不涉及相關基因研究者。
Do not involve new medical technology, new drugs,new medical devices, the bioavailability and bioequivalence of generic drugs, or related genetic research.

B. 不涉及個人隱私、不侵犯個人權益、不傷害受試者情感的研究計畫。
Do not involve personal privacy, infringe personal rights and benefits, or harm the emotion of subjects.

C. 最小風險的研究計畫。
Studies with minimal risk.

D. 已經或即將進行醫療所蒐集的資料、樣本之研究。
The protocol involves data collection or sample research of treatments that have been or will be implemented.

E. 其他有關符合衛生主管機關規定簡易審查範疇之研究計畫。
Other studies complying with the scope of expedited review specified by the health competent authority.

5.3.6.3. 經聯合人體試驗委員會(JIRB)、國家衛生研究院倫理委員會(NHRI-IRB)、衛生福利部人體試驗委員會主審中心(C-IRB) 及簽訂「臨床試驗聯盟聯合倫理審查機制議定書」，或醫院「合作協議書」之人體試驗委員會審查之計畫，其審查包括科學審查及倫理審查。

The review of projects that have been approved by JIRB, NHRI-IRB, C-IRB, and the IRB signing the NRPB-IRB Agreement or the hospital Cooperation Agreement shall include the scientific review and ethics review.

5.3.6.4. 執行秘書若遇特殊狀況，例如：易受傷害族群或有委員質疑進行簡易審查的合理性，將改為一般審查程序進行方式，並通知計畫主持人審查方式改變。計畫主持人不願意變更審查方式時，則逕入審查會說明及討論。

In case of a special situation, such as vulnerable groups or doubts about the fairness of an expedited review by an IRB member, the executive secretary shall change the review to a full board review and notify the principal investigator of the review change. When the principal investigator is unwilling to change the review, the presentation and discussion of the review meeting will be proceeded directly.

5.3.6.5. 若為一般審查案件，則安排入審查會日期。

Protocols for full board review shall be arranged in the review meeting schedule.

5.3.6.6. 行政人員須確認收案後2個工作日內完成分案。

Administrative staff shall complete the protocol assignment within two (2) workdays after acceptance.

5.3.7. 執行秘書依利益迴避原則、委員專長及審查案件量，以新案分案表(附件五)分派案件給二個委員會的審查委員，一人為醫療科技人員(相關專業背景)，一人為非醫療科技人員，進行科學性及倫理審查。

Based on the principle of avoidance of conflict of interest, the expertise of IRB members, and the loading of protocol review, the executive secretary shall assign a protocol to members of the two IRBs with the New Protocol Assignment Form (Attachment 5). One IRB member shall be specialized in medical technology (or related backgrounds) and one member shall be specialized in non-medical technology to conduct the scientific review and ethics review.

5.3.7.1. 執行秘書認為該計畫超乎委員所熟悉的專業範圍時，得邀請專家進行科學性審查；特殊案件之審查得邀請其他專家或受試者(團體)代表提供諮詢意見或列席會議參與討論。

When the executive secretary believes that a protocol exceeds the expertise of IRB members, he/she may invite experts to conduct the scientific review. The executive secretary may invite other experts or subject (group) representatives to provide consultative opinions or attend a review meeting and discussion as guests for the review of special protocols.

5.3.7.2. 可能涉及易受傷害族群的研究，在會議當中需有熟稔族群狀況的委員/專家得以出席、視訊或電話即席回答的方式提出意見同步參與討論、釋疑及協助委員會做成決議，並記載於會議紀錄當中。

If a protocol may involve vulnerable group research, IRB members/experts familiar with vulnerable groups may be invited to express opinions, join the discussion, ease the doubts, and assist IRB in making resolutions by attending the meeting or through videoconferencing or over the phone, and records shall be maintained in the minutes of meeting.

5.4. 審查計畫案

Protocol review

5.4.1. 行政人員準備初審審查意見表(附件六)及送審文件送交審查委員進行審查。
Administrative staff shall prepare the Initial Review Comments Form (Attachment 6) and submittals and send them to IRB members to proceed with the review.

5.4.2. 審查委員審查前須先確認是否須利益迴避。若審查委員需利益迴避，須通知執行秘書重新分派審查委員。
Prior to the review, IRB shall confirm the need for avoidance of the conflict of interest. An appraiser requiring avoidance of the conflict of interest shall notify the executive secretary to re-assign another appraiser.

5.4.3. 審查委員須於5個工作日內完成初審審查意見表。若委員發現遺漏審查資料，則應告知行政人員。
IRB shall complete the Initial Review Comments Form (Attachment 6) within five (5) workdays. Appraisers discovering unreviewed data shall inform administrative staff.

5.4.3.1. 依科學專業及倫理原則審查計畫書內容。
Appraisers shall review a protocol based on science expertise and ethical principles.

5.4.3.2. 一般審查另勾選是否邀請科學審查或其他諮詢專家或受試者(團體)代表列席或提供書面資料。
In a full board review, consider the need to invite experts for scientific review and other consultation or subject (group) representatives to attend the review meeting as guests or provide written data.

5.4.3.3. 簡易審查須勾選「核准」、「建議修正」或「不符合簡易審查」，若有疑慮時得提請入會討論，此時得視情況邀請科學審查或其他諮詢專家或受試者(團體)代表列席或提供書面資料。
In an expedited review, tick/check “approved”, “correction recommended”, or “unqualified for expedited review”. When there are doubts, request for a discussion meeting. In this case, consider the need to invite experts for scientific review and other consultation or subject (group) representatives to attend the review meeting as guests or provide written data.

5.4.3.4. 勾選追蹤審查頻率。
Tick/check the follow-up review frequency.

5.4.3.5. 初審申請表視為完成初審審查的正式文件。
The initial review application form shall be considered as an official document for completing the initial review.

5.4.4. 審查委員不核准免受試者同意書之計畫案，計畫主持人需檢送受試者同意書並重新送審。
IRB will not approve protocols without ICF. The principal investigator shall submit ICF and re-submit the protocol for review.

5.5. 人體研究新案/變更案/期中報告同意證明書(附件七)的核發有效期限，每次以一年為限。
The validity of the Certificate of Approval of New Protocol/Protocol Change/Interim Report of Human Subject Research (Attachment 7) shall be one year.

5.5.1. 核准日(審查通過日)：核准計畫的第一日。
Date of approval (date of review approval): Day one of protocol approval.

5.5.2. 核准到期日：核准日起第 364 日。有效期限到期後不能再執行研究。例如：試驗案核准期間為西元 2017 年 1 月 1 日至 2017 年 12 月31 日，其受試者同意書及計畫書在

2017 年 12 月 31 日 24 時過後失效。
Approval Expiry Date: Day 364 after the date of approval. A research shall be canceled after the expiry date. For example, if the validity of a trial is from January 1, 2017 to December 31, 2017, ICF and protocol will expire after 24:00 on December 31, 2017.

5.5.3. 正本留存於人委會，副本上傳PTMS系統供計畫主持人自行下載。
IRB shall retain the one original copy and upload the duplicate copy to the PTSM system for the principal investigator to download.

5.6. 初審審查結果通知
Notification of initial review results

5.6.1. 一般審查
Full Board Review

5.6.1.1. 行政人員彙整委員初審審查意見，排入原委員會議審議。
Administrative staff shall gather the initial review opinions of appraisers and schedule them in the IRB meeting for discussion.

5.6.1.2. 審查會議審議結果得為下列之決定：
The IRB meeting may make the following decisions:

A. 【核准】：主持人依審查會意見修改，交由原審委員/專家複審通過，經行政人員確認相關文件版本無誤後，於10 個工作日內，製作人體研究新案/變更案/期中報告同意證明書(附件七)送交主任委員簽名。
[Approved]: After revising the protocol based on the review opinion, the principal investigator shall submit the revised protocol to the original appraisers/experts for a second review and approval. After confirming that no error is found in the version of related documents, administrative staff shall produce the Certificate of Approval of New Protocol/Protocol Change/Interim Report of Human Subject Research (Attachment 7) within 10 workdays and submit it to the IRB chairperson for signing.

B. 【修正後複審】：行政人員應於會議結束後7個工作 日內，將會議審議結果，以新案/變更案/期中報告審議結果通知表(附件八)通知申請人/計畫主持人及試驗委託者。主持人依審查會意見修改，以複審案方式送審，交由原審委員/專家複審後，須等待入會決議，同意後核發同意證明書。
[Second Review after Correction] Administrative staff shall notify the applicant /principal investigator and sponsor of the review results within seven workdays after the end of the review with a Notice of Review Results of New Protocol/Protocol Change/Interim Report (Attachment 8). After revising the protocol based on the review opinion, the principal investigator shall submit the revised protocol for a second review. After the original appraisers/experts review and approve the revised protocol, it will be submitted to the IRB meeting for approval before issuing the certificate of approval.

C. 【修正後重新送審】：行政人員應於會議結束後7個工作 日內，將會議審議結果，以新案/變更案/期中報告審議結果通知表通知申請人/計畫主持人及試驗委託者。主持人依審查會意見修改後，須於下次審查會議再次列席。
[Re-submission for Review after Revision]: Administrative staff shall notify the applicant/principal investigator and sponsor of the review results within 7 workdays after the end of the review with a Notice of Review Results of New Protocol/Protocol Change/Interim Report (Attachment 8). After revising the protocol according to the review opinion, the applicant/principal investigator and sponsor shall attend the next

review meeting as guests.

D. 【不核准】：不予通過，退件。行政人員應於會議結束後7個工作 日內，將會議審議結果，以新案/變更案/期中報告審議結果通知表通知申請人/計畫主持人及試驗委託者，並詳細說明不核准理由。計畫主持人如需申覆，應於 14 個工作日內以書面資料提出。若未於期限內提出申覆，則依原審議結果辦理。
[Rejected]: A rejected protocol will be returned to the applicant/principal investigator and sponsor. Administrative staff shall notify the applicant/principal investigator and sponsor of the review results and explain the reason(s) of rejection within 7 workdays after the end of the review with a Notice of Review Results of New Protocol/Protocol Change/Interim Report (Attachment 8). The principal investigator wishing to appeal shall file a written appeal within 14 workdays. When no appeal is filed by the deadline, the protocol will be handled according to the original decision.

5.6.1.3. 審查決議核准或修正後複審之計畫案，修正資料未依委員意見或未於3個月內回覆人委會者，本會將逕予撤案。撤案後，計畫主持人須以新案方式重新送審。
After a revised protocol is approved or rejected by the IRB resolution, when the principal investigator fails to revise the protocol according to the appraiser's opinion or reply IRB within 3 months, IRB shall withdraw the protocol, and the principal investigator must submit the protocol for review as a new protocol.

5.6.2. 簡易審查
Expedited review

5.6.2.1. 委員填寫初審審查意見表， 送交工作人員，並將結果提報委員會備查。
Appraisers fill in the Initial Review Comments Form (Attachment 6) and send it to administrative staff to report the outcomes to IRB for reference.

5.6.2.2. 委員審查結果得為下列之決定：
Appraiser review may include the following decisions:

A. 【通過】：須排入會期核備，行政人員於會議結束後 10 個工作日內，製作人體研究新案/變更案/期中報告同意證明書送交主任委員簽名後，核發同意證明書。
[Approved]: An approved protocol shall be scheduled in the IRB meeting for reference. Administrative staff shall produce the Certificate of Approval of New Protocol/Protocol Change/Interim Report of Human Subject Research (Attachment 7) within 10 workdays after the meeting and submit it to the IRB chairperson for signing before issuing it to the applicant/principal investigator.

B. 【建議修正】：行政人員將委員初審審查結果彙整後，以新案/變更案/期中報告審議結果通知表通知申請人/計畫主持人進行修正，輕微敘述變更或要求, 由原主審委員審查通過後，行政人員於會議結束後 10 個工作日內，製作人體研究新案/變更案/期中報告同意證明書送交主任委員簽名後，核發同意證明書。申請人/計畫主持人如未於三個月內回覆，人委會 將逕行撤案。計畫主持人不願意依審查意見修正時，逕予提審查會討論。
[Revision Recommended]: After gathering the initial review results of appraisers, administrative staff shall inform the applicant/principal investigator to make revision with the Notice of Review Results of New Protocol/Protocol Change/Interim Report (Attachment 8) with hints of change or requirements. After the original appraisers approve the revised protocol, administrative staff shall produce the Certificate of Approval of New Protocol/Protocol Change/Interim Report of Human Subject Research

(Attachment 7) within 10 workdays after the meeting and submit it to the IRB committee director for signing before issuing it to the applicant/principal investigator. If the applicant/principal investigator fails to reply within 3 months, IRB will directly withdraw the protocol. When the principal investigator refuses to revise the protocol according to the review opinion, the protocol will be directly discussed at the IRB meeting.

C. 【不符合簡易審查】：以新案/變更案/期中報告審議結果通知表通知申請人/計畫主持人，建議改送一般審查。
[Unqualified for Expedited Review]: Administrative staff shall notify the applicant/ principal investigator to re-submit the protocol for a full board review with the Notice of Review Results of New Protocol/Protocol Change/Interim Report (Attachment 8).

5.7. 文件歸檔依標準作業程序6.1規定辦理。
Documents shall be filed in accordance with section 6.1 of t SOP.

6. 附件 Attachment

6.1. 附件一(KMUH/IRB/AF/2.3-01/11.2) 初審案申請表
Attachment 1 (KMUH/IRB/AF/2.3-01/11.2) Initial Review Application Form

6.2. 附件一.1(KMUH/IRB/AF/2.3-01.1/11.0)試驗藥品/疫苗簡介資料表
Attachment 1.1 (KMUH/IRB/AF/2.3-01.1/11.0) IND/Vaccine Datasheet

6.3. 附件一.2(KMUH/IRB/AF/2.3-01.2/11.0)醫療器材或醫療器材合併新醫療技術簡介資料表
Attachment 1.2 (KMUH/IRB/AF/2.3-01.2/11.0) Medical Device or Medical Device with New Medical Technology Datasheet

6.4. 附件一.3(KMUH/IRB/AF/2.3-01.3/11.0)醫療技術簡介資料表
Attachment 1.3 (KMUH/IRB/AF/2.3-01.3/11.0) Medical Technology Datasheet

6.5. 附件二(KMUH/IRB/AF/2.3-02/11.0)簡易審查範圍查檢表
Attachment 2 (KMUH/IRB/AF/2.3-02/11.0) Expedited Review Scope Checklist

6.6. 附件三(KMUH/IRB/AF/2.3-03/11.0)臨床研究人員利益衝突宣告揭露聲明書
Attachment 3 (KMUH/IRB/AF/2.3-03/11.0) Declaration of Conflict of Interest of Clinical Investigators

6.7. 附件四(KMUH/IRB/AF/2.3-04/11.0)資料及安全性監測計劃
Attachment 4 (KMUH/IRB/AF/2.3-04/11.0) Data and Safety Monitoring Plan (DSMP)

6.8. 附件五(KMUH/IRB/AF/2.3-05/11.0)新案分案表
Attachment 5 (KMUH/IRB/AF/2.3-05/11.0) New Protocol Assignment Form

6.9. 附件六(KMUH/IRB/AF/2.3-06/11.0)初審審查意見表
Attachment 6 (KMUH/IRB/AF/2.3-06/11.0) Initial Review Comments Form

6.10. 附件七(KMUH/IRB/AF/2.3-07/11.0)人體研究新案/變更案/期中報告同意證明書
Attachment 7 (KMUH/IRB/AF/2.3-07/11.0) Certificate of Approval of New Protocol/Protocol Change/Interim Report of Human Subject Research

6.11. 附件八(KMUH/IRB/AF/2.3-08/11.0)新案/變更案/期中報告審議結果通知表
Attachment 8 (KMUH/IRB/AF/2.3-08/11.0) Notice of Review Results of New Protocol/Protocol Change/Interim Report

6.12. 附件九(KMUH/IRB/AF/2.3-09/11.0) Delegation of Duties Log