1. 目的Purpose

為使人委會審查委員了解審查重點及記錄申請案的審查意見。

For committee members to understand the review criteria and comments for the protocol applications.

2. 適用範圍 Scope

所有向人委會提出申請初審的審查計畫案。

All protocols applied for initial review with the IRB.

3. 參考文件References

3.1 藥品優良臨床試驗規範(2002 年 08 月)

Guidance for Industry: Good Clinical Practice (August 2002)

3.2 醫療器材管理辦法(2017 年 7 月)

Regulations for Governing the Management of Medical Device (July 2017)

3.4 藥品優良臨床試驗準則(2014 年 10 月)

Regulations for Good Clinical Practice (October 2014)

3.5 臨床試驗受試者招募原則(2006 年 6 月)

Principles for Recruitment of Clinical Trial Subjects (June 2006)

3.6 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)

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

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

3.9 Ethical Guidelines for Biomedical Research on Human Subjects, 2000.

4.名詞定義 Terminology

4.1 初審審查意見表：審查委員/專家初次審查計畫案所使用之意見表，為計畫審查的正式記錄。

Initial Review Comments Form: opinion form used by the reviewer/expert for initial review and is an official record of protocol review.

4.2 紀錄：記載形式包括紙本、電子郵件、傳真、錄音帶及錄影帶等。

Record: in the form of written texts, e-mails, facsimile, audio and videotapes.

4.3 易受傷害族群：包括(1)未成年、(2)生存力不明之新生兒、(3)新生兒出生後確定不能存活者、(4)孕婦、(5)受刑人(含未成年及成年人)、(6)員工與學生、(7)原住民、(8)社區或特定族群(難民、經濟能力差、教育程度較低)、(9)決定能力欠缺之成年人。

Vulnerable population: include (1) minors, (2) newborns with unknown survivability, (3) newborns that cannot survive after birth, (4) pregnant women, (5) inmates (including minors and adults), (6) employee and student (7) aboriginals, (8) community or specific population (refugees, poor financial status, low education level), and (9) adults who lack the ability to make decisions.

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: the chances or degrees of mental or physical injuries that are equivalent to what a healthy subject receives during normal daily life, routine medical and psychological examinations, and have not been increased by participation in the clinical study.

4.5 第一類風險：相當於最小風險。

Type 1 risk: Equivalent to minimal risk.

4.6 第二類風險：超過最小風險，但對受試者有直接利益。

Type 2 risk: above minimal risk, but directly benefits the test subject.

4.7 第三類風險：超過最小風險，但對受試者無直接利益，但有助於了解受試者之情況。

Type 3 risk: exceeds minimum risk, has no direct benefit to the test subject, but can help to delineate information about the test subject.

4.8 第四類風險：超過微小風險，且對受試者無直接利益，但研究主題可得到價值的結果。

Type 4 risk: exceeds minimum risk, has no direct benefit to the test subject, but the research can potentially yield valuable results.

4.9 醫療器材：藥事法第 13 條所稱醫療器材，係包括診斷、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: as used in Article 13 of the Pharmaceutical Affairs Act, refer to any instruments, machines, apparatus, materials, tools, accessories and other similar or related articles, which is used in diagnosing, curing, alleviating, or

directly preventing human diseases, or which may affect the body structure or functions of human beings.

4.10 無顯著風險醫療器材(低風險性)：沒有顯著風險的實驗醫療器材。

Medical device with no significant risks (low risk): trial medical devices that do not have significant risks.

4.11 有顯著風險醫療器材(中風險性、高風險性)：指實驗醫療器材 (1)可能對受試者的健康、安全或福祉產生嚴重的傷害。 (2)為促使人體生命延續，而可能對受試者的健康、安全或福祉產生嚴重的傷害。 (3) 用於疾病的診斷、減緩、治療或避免惡化，而可能對受試者的健康、安全或福祉產生嚴重的傷害。

Medical device with significant risk (medium or high risks): medical devices that (1) may cause serious damages to the health, safety and welfare of the test subject, (2), may cause serious damages to the health, safety and welfare of the test subject in the attempt to prolong human life, and (3) may cause serious damages to the health, safety and welfare of the test subject in the attempt to diagnose, alleviate, treat or prevent worsening of the disease condition.

5.作業內容 Scope of operation

5.1流程 Process

流程 Process	**權責** **Rights and responsibilities**
審查前置作業 Prepartion for review	申請人/計畫主持人/行政人員 Applicant/Principal Investigator/Adminstrative staff
填寫初審審查意見表 Completing Initial Review Comments Form	審查委員/專家 Reviwer/Expert
審查意見彙整、確認及通知 Compiling opinion forms, verification and notification	行政人員 Adminstrative staff
歸檔 Filing	行政人員 Adminstrative staff

5.2職責Responsibilities

5.2.1 審查委員/專家：將評審意見及決定記錄於初審審查意見表。

Reviewer/expert: record the reviewer's opinions and decisions in the Initial Review Comments Form.

5.2.2 主任委員：一般審查計畫案分案

Committee director: distribute the general protocol review.

5.2.3 執行秘書：基因、特殊族群、簡易審查計畫案分案

Executive secretary: distributes the genomic, special population and expedited review protocols.

5.2.4 行政人員：將相關審查意見與結果彙整後送給申請人/計畫主持人並歸檔。

Administrative staff: compile all opinion forms and results, deliver to the applicant and principal investigator, and archiving the information.

5.3流程Procedure

5.3.1 審查前置作業

Preparation for review

5.3.1.1 申請人/計畫主持人依據送審文件清單提交送審相關文件；行政人員確認送審文件齊全。

The applicant/principal investigator submit the documents for review according to the review document checklist; the administrative staff verifies that the document is complete.

5.3.3.2 主任委員/執行秘書分案後，行政人員將計畫案送交審查委員。

The committee director/executive secretary distributes the protocols, which are then sent by the administrative staff to the reviewers.

5.3.2 審查重點

Key points of review

5.3.2.1 執行試驗的條件

Criteria for clinical trial

A.計畫主持人及研究人員資格(學經歷、專業)之適當性。

The suitability of the qualification of the principal investigator and research personnel (educational and professional experiences, expertise).

B.試驗所需設備、設施、及處理緊急狀況之能力。應注意是否使用輻射性物品

Equipment and facility needed for the trial; ability to handle emergency situations; and shall notice the use of radiological material.

C.試驗的時間和人力是否足以執行與完成試驗。

Whether the time and manpower is sufficient to implement and complete the study.

D.多中心之研究是否具備聯絡溝通管道。

Whether channels for communication are available in a multi-center study.

E.主持人及研究人員之利益衝突評估

Assessment of conflicts of interests in principal investigator and researcher.

(A)主持人及研究人員執行業務之所得費用須合理。

The fees provided for the principal investigator and researcher to carry out the tasks should be appropriate.

(B)研究執行嚴禁給予介紹費、轉介費及額外獎勵。

Finder's fees, referral fees and bonus payments are prohibited.

5.3.2.2.研究計畫案

Study protocol

A.研究設計的合理性(尤其是對照組之選擇)

Suitability of study design (especially the selection of control group)

B.研究假設的明確性

Clarity of study hypothesis

C.研究設計可證明研究假設

The study design is able to verify the study hypothesis

D.樣本數計算的合宜性

The suitability of sample counts

E.風險與利益評估

Risk and benefit assessment

(A)研究步驟及執行過程，有考量降低受試者的風險。

The study procedures and implementation have taken into consideration to lower the risks of the test subjects.

(B)研究案考慮盡可能使用已有的檢驗或檢查的資料，而不新增受試者風險與不適。

The study protocol has considered using as much of existing tests or test data as possible and avoids increasing discomforts and risks for the test subjects.

(C)風險的分類評估：藥品風險分屬第一類風險/第二類風險/第三類風險/第四類風險。醫療器材分屬無顯著風險(第一等級：低風險性) /顯著風險(第二等級：中風險性、第三等級：高風險性)。

Risk classification assessment: risks of medication are Type1/Type2/Type3/Typ4; risks of medical devices are non

significant risks (Type 1: low risks)/significant risks (Type 2: medium risks, Type 3: high risks)

(D)有資料安全監測委員會/計畫(DSMB/DSMP)之設置。(詳見 SOP 3.2評估資料及安全性監測計畫之必要性)

The protocol has plans for DSMB and DSMP. (please see SOP 3.2 for the necessity of assessing data and safety monitoring plan)

F.主持人手冊

Investigator's brochure

(A)依據試驗產品非臨床及臨床研究之科學及安全性資料，評估本計畫案執行之可行性。

Evaluate the feasibility of the trial product protocol based on the scientific and safety data from non-clinical and clinical research.

(B)依據主持人手冊內容，評估同意書已提供足夠訊息給受試者。

Check that the informed consent form has provided sufficient information to the subject based on the content of the investigator's brochure.

G.受試者族群選擇

Selection of subject population

(A)受試者納入/排除條件

Inclusion/exclusion criteria

(B)選擇受試者族群（包括教育、文化、經濟、職業別及種族淵源、無法行使同意者、易受傷害族群...等）符合公平正義原則，需考量：

The selection of subject population (including education, culture, financial, occupation and ethnicity, individuals unable to make decisions and vulnerable populations) should comply with the principles for justice and fairness:

a.不能取決於其便利性或易受操縱性。

Cannot depend on convenience or susceptibility to manipulation.

b.無法自研究後續的應用而受益之族群，不得列為受試者。

Populations that cannot benefit from subsequent application of the study cannot be recruited as subjects.

c. 若預期會有顯著利益，選取受試者的來源應儘可能遍及各種不同的族群。

If significant benefits are expected, the sources of subjects should include as much of diverse populations as possible.

d. 納入弱勢族群／團體之研究議題必須有科學上之合理性，且有額外之保護措施以避免脅迫或不當影響之可能性。

Topics that include vulnerable populations or groups must have scientific rationale and must employ extra protective measures to prevent the possibilities of threats and undue influence.

(a)對於經濟弱勢受試者，須考慮報酬是否強烈影響到個人參與研究的自主性。

For subjects of poor financial status, consider whether the promised rewards have strongly affected the personal free-will in participating in the study.

(b)對於教育弱勢受試者，須確保其完全了解受試者同意書。

For subjects with low education level, consider whether the subjects truly understand the content of the informed consent form.

e. 納入學生或員工為受試者，需要符合以下條件：

Inclusion of students or employees as subjects must fulfill the following criteria:

(a)研究者或與研究相關的人員，不直接評核參與研究之學生的學業表現。

The investigator or research staff shall not directly evaluate the academic performances of students participating in the study.

(b)研究者或與研究相關的人員，不直接評核參與研究之員工的工作表現。

The investigator or research staff shall not directly evaluate

the work performances of employees participating in the study.

(c)應使用公開招募方式進行，不得個別徵詢。

The recruitment should be openly conducted and individual invitation is not allowed.

f.考量易受傷害族群參與試驗之適當性（詳見 SOP 2.4 社區研究、易受傷害及決定能力缺乏受試者保護）。

Should consider the suitability of including vulnerable populations into the study (please see SOP 2.4 Protection of subjects for community study, vulnerable populations and individuals unable to make decisions)

H. 受試者之照護方面

Care for tests subjects

(A)對受試者心理及社會層面之支持。

Provides psychological and social support for the test subjects.

(B)為試驗目的而取消或暫停標準治療之合理性。

The rationale for cancelling or suspending standard treatments for study purposes.

(C)試驗期間及試驗後，提供受試者之醫療照護。

Medical care provided to the subjects during and after the study period.

(D)試驗產品延長使用、緊急使用及恩慈使用之標準。

The standards for extended usage, emergency usage and compassionate usage of study products.

(E)計畫結束後，提供受試者繼續取得試驗產品之計畫。

Plan to continue supplying study products to the subjects after the study has completed.

I. 計畫中止/暫停機制

Mechanisms for study termination and suspension

(A)受試者提前退出試驗之條件。

Criteria for subject's pre-mature withdrawal from the study

(B)暫停或中止全部試驗的條件。

Criteria for suspending or terminating all studies

(C)試驗過程中，受試者自願退出時，將採取之步驟。

Measures taken for voluntary subject withdrawal during the study.

J. 試驗結果之報告或發表方式

Publication of study results or reports

5.3.2.4 免除受試者書面同意且不需說明應評估是否符合相關條件（詳見 SOP 2.6 免除或改變知情同意）。

Assess whether waiver of informed consent without explanation is appropriate (please see SOP 2.6 on waiver or alteration of informed consent).

5.3.2.5 受試者同意書程序

Procedure of informed consent form

A. 招募方式、廣告的合理性

Suitability of recruitment format and advertisement

(A)應符合臨床試驗受試者招募原則（依據衛署藥字第 0960317637 號函）。

Recruitment of clinical trial subjects shall follow the "Principles on recruitment of tests subjects for clinical trials" (promulgated via Letter Wei-Shu-Yao-Zi No.0960317637).

(B)招募廣告不得有下列內容或類似涵意之文字：

Recruitment advertisement may not contain the following or texts with similar meanings:

a.宣稱或暗示試驗藥品為安全、有效或可治癒疾病。

Claiming or implying that the trial medication is safe, effective or can cure disease.

b.宣稱或暗示試驗藥品優於或相似於現行之藥物或治療。

Claiming or implying that the trial medication is better than or similar to medication or treatments currently in use.

c.宣稱或暗示受試者將接受新治療或新藥品，而未提及該研究屬試驗性質。

Claiming or implying that subjects will receive new therapy or

medication without mentioning the experimental nature of the study.

d.強調受試者將可獲得免費醫療或費用補助。

Emphasizing that subjects will receive free medical care or subsidies.

e.強調臨床試驗已經衛生主管機關或人體試驗委員會核准。

Emphasizing that the clinical trial has been approved by competent health authority agency or the IRB.

f.使用名額有限、即將截止或立即聯繫以免向隅等文字。

Texts that contain the following (or similar in meaning): Limited placement, offer expires soon and contact immediately before it's too late.

g.使用含有強制、引誘或鼓勵性質之圖表、圖片或符號。

Usage of graphs, graphics or symbols that are compulsory, luring or encouraging.

h.其他經中央衛生主管機關公告不得刊登之內容。

Other contents prohibited by announcement from the central competent health authority agency.

(C)得刊載內容

Recruitment advertisement should contain the following:

a.試驗主持人姓名及地址。

Name and address of the principal investigator.

b.試驗機構名稱及地址。

Name and address of the trial institution.

c.試驗目的或試驗概況。

Purpose and background of the trial.

d.主要納入及排除條件。

Inclusion and exclusion criteria.

e.試驗之預期效益。

Expected benefits of the trial

f.受試者應配合事項與試驗期間。

Matters requiring cooperation from the subjects and the study period.

g.試驗聯絡人及聯絡方式

Trial contact persons and contact methods.

(D)付款給研究員

Payment for the research personnel

a.不允許支付發現費、介紹費(finder's fees)、轉介費(referral fees)及額外獎勵 (bonus payment)

Finder's fees, referral fees and bonus payments are not allowed.

b.不允許加速招募的招募獎金。

Bonuses for accelerated recruitment are not allowed.

B. 同意書取得的方式的合理性

Suitability of obtaining informed consent form

(A)評估向受試者解釋同意書之人員、時機、地點之適當性

Evaluate the suitability of the person describing the ICF, timing and location

(B)知情同意過程須降低強迫或不當影響的可能性。

The procedure of informed consent should lower the possibility of coercion and undue influence.

(C)以可理解的方式向受試者(及其家屬)說明同意書內容。

Describe the content of the informed consent form to the subjects and family members in an easily understood format.

(D)給予受試者足夠時間考慮、溝通，並告知隨時可提出問題。

Give subjects sufficient time to consider and communicate; inform subjects that questions may be asked at any time.

(E)不能有放棄任何受試者的合法權益的免責文字。

Disclaimer texts on abandonment of the due rights of test subjects are not allowed.

(F)不能有讓研究者/贊助者/機構免除過失侵權責任的免責文字。

Disclaimer texts that exempts the investigator/sponsor/institution from liability of infringements and faults.

(G)須由受試者本人、法定代理人或是有同意權人簽署知情同意書及日期。

The informed consent form must be signed and dated by the test subject, legal representative or authorized person.

(H)依據法規提供每位受試者(或其法定代理人)完整同意書訊息，以及額外須要揭露的訊息。

According to the law, the complete information of the informed consent form and any extra information must be fully disclosed to the subject (or the legal representative).

(I)進行臨床試驗計畫，取得同意者、獲得知情同意者姓名、取得時間、取得方式應記錄於病歷。

The methods of obtaining the names of the informed consent giver, the time and method should be recorded in the medical record of subjects undergoing clinical trials.

C. 受試者同意書內容

Contents of the informed consent form

(A)說明本受試者同意書已經本醫院人委會審核通過

Explain that the informed consent form has been approved by the IRB.

(B)研究背景簡介說明受試者的總人數、國內人數、本院人數

Explain the total number of subjects, domestic subjects and hospital subjects in the introduction of study background.

(C)試驗目的

Purpose of the study.

(D)受試者之納入及排除條件

Inclusion and exclusion criteria.

(E)試驗方法、程序與相關檢驗

Study methods, procedures and related tests.

a.涉及檢體採集須加強說明檢體採集之目的及其可能使用範圍與使用期間；檢體採集之方法、種類、數量、部位及使用用途。

Describe the purpose of specimen collection, its usage and period of its usage: methods of specimen collection, types, quantities, locations and purpose.

b.依據計畫書要求，說明所需檢體採集、病歷紀錄、追蹤檢測或疾病訊息等。

Describe the following as required by the protocol: specimen collection, medical record, follow-up tests and disease information.

c.剩餘檢體之處理方式

Disposal of residual specimen

(a)檢體提供者之權益、檢體及相關資訊使用者及保管者之姓名及責任

The rights of specimen provider, names and responsibilities of the specimen and information users and keepers.

(b)檢體是否有提供、讓與或授權國內或國外之他人使用檢體之情形。檢體輸出境外，須符合人體生物資料庫管理條例。

Describe whether the specimen is to be provided, offered or authorized for usage by domestic or foreign parties. Exportation of human specimen must comply with the Human Biobank Management Act.

d.剩餘檢體之地點及保存期限。

Location and expiry period of storage of residual specimen.

e.研究經費的來源及所有參與研究的機構。

The source of research funding and all participating institutions.

f.基因研究與處置是否合宜

Whether the genomic study and procedures are appropriate.

(F)可能產生之副作用、發生率及處理方法

Possible side effects, incidence rate and treatment methods

(G)其他替代療法及說明，陳述現有的替代療法及可能的效益與風險

Description of other alternative therapies; describe the available alternative therapies and possible benefits and risks

(H)試驗預期效益

Expected benefits of the clinical trial

(I)試驗進行中受試者之禁忌、限制與應配合之事項(如：參與時間、次數...等)

Prohibition, limitation and matters requiring cooperation of the test subjects (e.g. participation period, frequency, etc.)

(J) 受試者隱私及資料保密及保存措施，包括

Protection of subject's privacy and confidentiality of data, including

a.提供實際保護，讓參與者不會感到不舒服，並確保過程中，防止他人目擊、聽到或無意中查看受試者與研究人員的互動，包括互動地點、電話聯繫、郵件等。

Provide protection so the subjects do not feel uncomfortable. Ensure that the interaction between the subject and researchers are not overheard, witnessed or inadvertently observed by other people, including locations of interaction, telephone conversations and mail communications.

b.所收集的資料限制在完成研究目的所必需的最少資料量。

The data collected is limited to the minimum amount of data needed to complete the purpose of the study.

c.若受試者簽署同意書及同意其原始醫療紀錄可直接受監測者、稽核者、人委會及主管機關檢閱(試驗若受美國食品藥物管理局管轄，則主管機關包含美國食品藥物管理局)

Subject has signed the ICF and agree to have his/her original medical record accessible by trial monitor, auditor, IRB and competent health authority agency (if the trial is managed by

the U.S. FDA, then the competent health authority agency will include the U.S. FDA).

(K)補助、所需費用、損害賠償與保險

Subsidy, required expenses, damage compensation and insurance

a.參加試驗對受試者財務狀況之可能影響。

Possible effects on the financial status of subjects participating in the study.

b.計畫結束後是否提供受試者繼續使用試驗產品。

Whether the study products will be continuously provided to the tests subjects after the study has ended.

c. GCP 第 10 條 試驗委託者對於受試者可獲得之補助及付款方式，不得有強迫或不當影響受試者之情形。受試者之補助，應按臨床試驗進行之進度依比例給付之，不得於試驗完成後方為給付；補助按比例分配付款之方式應詳細說明。受試者補助之付款方式、金額及付款進度應載明於受試者同意書及其他給予受試者之書面資料。但小金額者，不在此限。

Article 10 of the Good Clinical Practice: In the aspect of amount and method of payment to subjects, the sponsor should not impose coercion or undue influences on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject; the way

payment will be prorated should be specified; information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, should be clearly stated in the written informed consent form and any other written information to be provided to subjects, except when the payment is a small amount.

(L)受試者權利

Rights of the subjects

a.於試驗期間，確保受試者獲得最新資訊。

Ensure that subjects are updated on the latest information during the study period.

b.提供諮詢或投訴並予以回應之機制。

Provide a channel for consultation request, grievance reporting and feedback.

c.當有爭議時，以試驗執行機構所在地之法院管轄。

Disputes will be resolved by the local court of law in the location of the trial organization.

(M)本研究預期可能衍生之商業利益及其應用之約定。

Expected potential commercial interests from the study and agreement of its application.

(N)試驗之退出與中止之處理方式

Withdrawal and termination from the study

(O)簽名欄位

Signature fields

a.免簽署受試者同意書評估是否符合相關條件（詳見 SOP 2.6 免除或改變知情同意）。

Whether the waiver of informed consent form fits with the criteria (please see SOP 2.6 waiver or alteration of informed consent)

b.受試者/法定代理人/有同意權人/見證人簽署之完整性

The completeness of the signatures of test subject/legal representative/authorized person/witness

(P)用詞為受試者可理解程度

The language and wording should be easily understandable by the test subject

(a) 內容口語化、明白易懂，潛在受試者可以了解(國中三年級程度)。

The content is described in a colloquial format that is easily understood by the test subject (equivalent to third-year junior high education level).

(b) 7~12 歲之兒童，需提供兒童版同意書，建議：(1) 加註注音符號。(2) 使用兒童可理解的詞句，避免使用專業術語。若需使用專業術語，宜附加解釋。(3)可使用圖示或插圖解說 。

For children age 7~12 years, a children's version of the ICF is required. The following are recommended: (1) Chinese phonetic notations are added to words; (2) use sentences and texts understandable by children and avoid using terminology; if terminology is used, provide explanation; (3) use diagrams or illustrations to aid in the explanation.

(Q)受試者因參與試驗而受傷、殘障或死亡時之賠償與治療。

The compensation and treatment offered to subjects who are injured, disabled or died from participating in the study

(R)賠償及保險之安排。

Arrangement for compensation and insurance

5.3.3 審查委員/專家審查結果

Results of review by committee member/expert

5.3.3.1 依照初審審查重點進行審查，並將審查意見填寫於初審審查意見表(附件 一)。

Conducts review according to the aforementioned key points, and fill out the Initial Review Comments Form (Attachment 1)

5.3.3.2 勾選審查結果

Checking off review conclusions

A. 一般審查須勾選是否邀請諮詢專家或受試者(團體代表)列席或提供書面意見。

For general review, select whether to invite consulting experts or

subjects (group representative) to attend the meeting or provide written comments.

B. 簡易審查之審查結果可為「核准」、「修正後複審」、「入會討論」。

The results of expedited reviews can be “approved”, “resubmit after revision” and “submit for discussion during meeting”.

a.核准：核發本會同意臨床試驗證明書。

Approval: issue an IRB certificate of approval of clinical trial.

b.修正後複審：輕微敘述變更或要求，由原主審委員審查通過，核發同意臨床試驗證明書。

Resubmit after revision: briefly describe the areas needed for alterations; review and approved by the original committee members, and issue an IRB certificate of approval of clinical trial.

c.提會討論：當有實質修正須至會議中討論及決議或主審認定無法以簡易審查核准此案。

Submit for discussion during meeting: revisions that need to be discussed during IRB meetings, or when the main reviewer decided that expedited review cannot be granted.

5.3.3.3 簡易審查不得為「不核准」之決定。

The decision of expedited review cannot be “rejected”.

5.3.3.4 檢查初審審查意見表的完整性與正確性。

Check the completeness and accuracy of the Initial Review Comments Form.

5.3.3.5將初審審查意見表提交 IRB 工作人員。

Submit the initial comments form to the IRB staff.

5.3.4初審審查意見彙整、確認及通知

Compiling, verifying and notification of initial review comments.

5.3.4.1一般審查案件

General reviews

A.工作人員將初審審查結果彙整後，排入會期討論。

Staff member compiles the results of the initial reviews and schedule for discussion during meetings.

5.3.4.2簡易審查案件

Expedited reviews

A.工作人員將初審審查結果確認表(簡易審查) (附件 2)送交秘書確認。

Staff member submit the Verification Form of Initial Review (Expedited Review) (Attachment 2) for confirmation by the secretary.

B.工作人員將初審審查結果通知表(簡易審查) (附件 3)通知申請人/計畫主持人。

Staff member sends the Notification of the Results of Initial Review (Expedited review)(Attachment 3) to the applicant or principal investigator.

5.3.5歸檔

Archiving of information

5.3.5.1計畫案原始資料、簡易審查初審審查意見表、初審審查結果通知表(簡易審查)、同意臨床試驗證明書應歸檔管理。

The original information of the protocol, initial expedited review comments form, notification of the results of initial reviews (expedited review) an certificate of approval of clinical trial should be archived accordingly.

5.3.5.2工作人員將資料放置指定位置存放。

Staff members should store the information in a specified location.

6.附件Attachment

6.1附件一(KMUH/IRB/AF/2.2-01/11.0)初審審查意見表

Attachment 1 (KMUH/IRB/AF/2.2-01/11.0) New Application of Initial Review Comments Form

6.2附件二(KMUH/IRB/AF/2.2-02/11.0)初審審查結果確認表(簡易審查)

Attachment 2 (KMUH/IRB/AF/2.2-02/11.0) Verification Form of Initial Review (Expedited Review)

6.3附件三(KMUH/IRB/AF/2.2-03/11.0)初審審查結果通知表(簡易審查)

Attachment 3(KMUH/IRB/AF/2.2-03/11.0) Notification of the Results of Initial Review (Expedited Review)