1. 目的 Purpose

為了讓人委會對於送審文件處理具一致性，制定本規範以落實送審文件管理。

This standard operating procedure (SOP) is established for the Institutional Review Board (IRB) to ensure the consistency of protocol submission management. (Ver. 1) The Kaohsiung Medical University has established this standard operating procedure (SOP) for the Institutional Review Board (IRB) to ensure the consistency of protocol submission management. (Ver. 2)

2. 適用範圍 Scope

本標準作業程序適用於所有送入人委會之各類送審文件。

This SOP shall apply to all documents submitted to IRB.

3. 參考文件 References

3.1 法規依據 Legal basis

3.1.1 藥品優良臨床試驗準則（2010 年 7 月）

Regulations for Good Clinical Practice (Jul 2010)

3.1.2 人體研究法(2011 年 12 月)

Human Subjects Research Act (Dec 2011)

3.1.3 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 Study (Aug 2012)

4. 名詞定義 Terminology

4.1 行政人員：執行人委會各項業務之人員。

Administrative Staff: Staff implementing various IRB business.

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**
申請人填寫送審資料 Completion of files for review by applicants	申請人 Applicant	送審文件清單 List of Files for Review
檢送申請資料 Submission of application documents	申請人 Applicant	送審文件 Files for review
行政審查 （文件是否齊全） Administrative Review (Check for submittal shortages)	行政人員 Administrative staff	送審文件清單 List of Files for Review

5.2 計劃案申請 Project application

5.2.1 申請人/計畫主持人自 IRB 網站下載申請文件並填寫相關表格。
An applicant/principal investigator shall download the application documents from the IRB website and fill in related forms.

5.2.2 申請人/計畫主持人依據送審文件清單（附件一）至線上申請系統申請，並檢附相關資料。
An applicant/principal investigator shall file an application to the online application system with respect to the List of Files for Review (Attachment 1) and submit related data.

5.2.3 行政人員依據人委會送審文件清單，進行行政審查，核對送審文件簽名、日期、版本等欄位皆已填寫完整。
Administrative staff shall implement the administrative review with respect to the IRB List of Submittal by checking if the signature, date, and version columns in the files for review are filled.

5.2.4 送審文件未齊全，併同申請送審資料退回申請人/計畫主持人。
When there is a submittal shortage, administrative staff shall return all files for review to the applicant/principal investigator.

5.3 審查流程/Process evaluation

5.3.1. 審查受試者納入與排除條件
Review of the acceptance and rejection criteria of subjects

5.3.1.1 審查委員於審查時，應考量公平正義之原則，評估研究計畫是否公平選擇受試者；並依照受試者參與各種類型研究所面臨之風險，考量研究對象納入與排除條件之合理性。
When conducting a review, IRB shall maintain the principle of fairness and justice to evaluate if subjects are fairly selected in a study. IRB shall also evaluate the fairness of the acceptance and rejection criteria of subjects in respect of the risks that all types of studies and subjects face.

5.3.1.2 審查委員於審查時，對於風險較高之研究，應要求對受試者須提供適當之保護措施，優先考量風險控制方法。若無法掌控受試者參加研究可能承受之傷害，則應列為排除（或限制納入）條件。
When reviewing a study, IRB shall request protective measures appropriate for subjects of studies with higher risks and prioritize the respective risk control methods. IRB shall list all potential irresistible risks on subjects as rejection criteria (or acceptance restrictions).

5.3.1.3 審查委員於審查時，須注意納入之受試者應以有意識能力之成年人為限。但研究顯有益於特定人口群或無法以其他研究對象取代者，不在此限。
When evaluating a study protocol, IRB shall ensure that all subjects accepted by the study shall be adults with self-cognition, except for studies that are beneficial to specific population groups or irreplaceable by other subjects.

5.3.1.4 審查委員於審查時，須注意受試者是否為易受傷害族群，如未成年人、受刑人、原住民、孕婦、精神病人等，審查時應兼顧研究之可執行性及所選擇族群之代表性。

When evaluating a study protocol, IRB shall check if subjects come from the vulnerable population, such as minors, prisoners, indigenous peoples, pregnant women, and psychotic patients. In the evaluation, IRB shall consider the executability of a study and the representativeness of selected subjects.

5.3.1.3 審查委員依「審查意見表」中「受試者之保護」之項目，逐項評估受試者選擇與排除條件、招募流程、受試者之風險及隱私權，確認符合倫理及法律規範。

IRB members shall evaluate the selection and rejection criteria of subjects, recruitment processes, and risks and privacy of subjects based on each item in the Subject Protection section of the Evaluation Sheet to ensure conformity (compliance) with study ethics and legal requirements.

5.3.2 審查受試者同意書之取得程序

Review of the procedures for collecting informed consent forms (ICFs)

5.3.2.1 受試者同意書的內容應符合赫爾辛基宣言的規定。

The information contained in ICF shall conform with the Declaration of Helsinki.

5.3.2.2 受試者同意書應載明下列事項：

ICF shall include the following items:

A. 研究背景/試驗目的
   Background of study/purpose of trials
B. 試驗之主要納入與排除條件
   Major acceptance and rejection criteria of trials
C. 試驗方法及相關檢驗
   Methodology and related examinations
D. 檢體/資料將如何處理、儲存地點及保存期限、誰可以使用您的檢體
   Processing, storage location, expiration, and access of specimens/data.
E. 可能產生的副作用、發生率及處理方法
   Possible side effects, incidence rate, and handling methods.
F. 其他替代療法及說明
   Other alternative treatments and descriptions
G. 預期效益
   Anticipated benefits
H. 試驗進行中受試者之禁忌、須限制與應配合之事項
   Contradictions, restrictions, and cooperation of subjects during the trial.
I. 研究結束後剩餘檢體處理方法
   Handling of residual samples after the study.
J. 身份紀錄及個人隱私資料的機密性
   Confidentiality of identity records and privacy data.

K. 損害賠償與保險
Damages and insurance

L. 受試者權利
Rights and interests of subjects

M. 可自由決定是否參加試驗，試驗過程亦可隨時撤銷同意，退出試驗，不會引起任何不愉快或影響日後醫師對受試者的醫療照顧
Subjects shall be entitled to voluntarily participate in the study, rescind informed consent, and withdraw from the trial during the trial without causing unpleasant feelings or affecting the services they will receive from physicians in the future.

5.3.2.3 解釋知情同意之流程
Processes of explaining the informed consent

A. 選擇適當之環境
Choose a suitable environment.

B. 必要時主要照顧家屬或有其他家屬須在現場
The major care-giving family or other family should be present where necessary.

C. 以淺顯易懂的方式向受試者(及其家屬)說明同意書內容
Explain in lay terms the contents of the ICF to the subject (and his/her family).

D. 給予受試者時間考慮、溝通，並告知隨時可提出問題，確認所需考慮的時間及了解如何聯繫
Give the subject time to consider and communicate, inform the participating that he/she can ask questions at any time, and confirm the time needed for consideration and understand the connection method.

E. 再次確認受試者是否了解同意書之內容，詢問是否有意願參與 此試驗或研究。
Re-confirm if the subject understands the contents of the inform consent form and ask if he/she is interested in participate in this trial or study.

F. 請受試者完成簽署同意書
Ask the subject to sign the ICF.

5.3.2.4 主持人納入受試者對象如為無法行使同意之人須進行知情同意程序，須依受試者同意書簽名欄規定執行知情同意程序。
If a subject accepted by the principal investigator cannot carry out the informed consent procedures, the informed consent procedures shall be implemented in accordance with the requirements specified in the signature of subject column.

5.3.2.5 審查委員於審查時應
In the evaluation, IRB members shall:

A. 依據「審查意見表」審查受試者同意書之內容及取得程序。受試者同意書須包括所有受試者於參與實驗前應被告知並須了解將參與之臨床試驗之相關訊息。審查委員須確認受試者是否能於斟酌參與試驗之所有因素後，自願參與試驗。

Review the contents and collection procedures of the ICF with respect to the Evaluation Sheet. The ICF shall include all information relating to the clinical trial that subjects should be informed of and understand before the clinical trial. IRB members shall confirm if subjects can consider all factors relating to the trial or study before participating in the trial or study voluntarily.

B. 注意臨床試驗進行前，試驗主持人或其指定之人員，是否能給予受試者、法定代理人或有同意權之人充分時間與機會，以詢問臨床試驗之細節，取得受試者自願給予之受試者同意書。
Check if the principal investigator of a trial or the staff he/she designates can give subjects, their legally acceptable representatives (LARs), or persons with consent entitlement adequate time and opportunities to ask questions regarding the details of the clinical trial before collecting ICFs presented voluntarily by subjects prior to the clinical trial.

C. 注意試驗主持人或由其指定之人員，是否能充分告知受試者臨床試驗進行之資訊、受試者同意書之內容及所有由人體試驗委員會所核准與臨床試驗相關之書面意見，並使用口語化及非專業性之語言，使受試者充分瞭解後親筆簽名，並載明日期。
Check if the principal investigator of a trial or the staff he/she designates can fully inform subjects of the information regarding the progression of the clinical trial, the contents of the ICF, and the written comments regarding the IRB approval and the clinical trial; and use everyday life and non-professional language for subjects to fully understand the trial prior to signing ICF and indicate the date of signing.

D. 確認計畫主持人可依法(GCP，醫療法，人體試驗管理辦法及人體研究法等)完成知情同意之取得。
Verify that the principal investigator can collect the ICFs according to the law (GCP, Medical Care Act, Regulations on Human Trials, and Human Subjects Research Act).

E. 評估計畫主持人於研究計畫執行期間，是否能確保研究對象及時得到與其權利、安全與福祉相關之最新資訊。若具有重要之新資訊可能影響研究對象之同意時，應修訂同意書內容及提供研究對象書面資料，並應立即告知研究對象。
Evaluate if the principal investigator can ensure that subjects obtain the latrial information relating to their rights, interests, safety, and well-being in real time during the study period. When there is important new information that may affect the consent of subjects, the principal investigator shall amend the contents of the ICFs and provide written data for subjects, and immediately inform subjects of such new information.

F. 要求計畫主持人於研究期間，建立研究對象之詢問或投訴並予以回應之機制。
Request the principal investigator to establish a mechanism to address and

respond to the enquiries and grievances filed by subjects during the study period.

G. 審視受試者同意書及提供受試者之任何其他書面資料，不得有任何會造成受試者、法定代理人或有同意權之人放棄其法定權利，或免除試驗主持人、試驗機構、試驗委託者或其代理商責任之記載。
Review the ICF of subjects and all other written data provided for subjects without making any remarks that can cause subjects, their LARs, or persons with consent entitlement to waive their rights or relieving the responsibility of the principal investigator, trial organization, trial client, or their agents.

5.3.3 **審查得免除受試者知情同意之程序**
Review of procedures allowed for the exemption of the informed consent of subjects

5.3.3.1 同時符合下列四項條件方可免除受試者同意書：
The informed consent of subjects can be omitted when all the following four requirements are met:

A. 研究計畫對受試者可能之風險需低於最低風險。
The potential risk on subjects of a study is below the minimum risk.

B. 免除「受試者同意書」後，對受試者的隱私與權益沒有不良的影響。
The exemption of the Informed Consent Form will cause no harm to the privacy, rights, and interests of subjects.

C. 不免除「受試者同意書」，則研究計畫無法進行。
The study cannot be proceeded without exempting the Informed Consent Form.

D. 免除「受試者同意書」後，仍會適時提供受試者試驗相關的訊息。
Subjects will be timely informed of related information after the exemption of the Informed Consent Form.

5.3.3.2 審查委員須依照研究風險之高低，評估研究計畫是否得免除知情同意之程序，並依前行政院衛生署 101 年 7 月 5 日衛署醫字第 1010265083 號公告訂定之「得免取得研究對象同意之人體研究案件範圍」判定是否得以免除知情同意之取得。
IRB members shall evaluate the procedures where the informed consent can be exempted in a study with respect to the level of study risks. IRB members shall also determine the need to collect ICF from subjects in accordance with the Scope of Human Study Subjects Allowed for Exemption of the Informed Consent of Subjects promulgated by Notice Wei-Shu-Yi-Zi (DOH-Medical Affairs) No. 1010265083 issued on July 5, 2012.

5.3.3.3 審查委員依照「免除書面知情同意、變更知情同意形式，或完全免除知情同意審查指引」審查免除受試者知情同意之程序
IRB members shall evaluate the procedures allowed for the exemption of the informed consent of subjects with respect to the Guidelines for the Exemption and Format Change of Informed Consent or the Full Exemption of Informed Consent Review.

5.3.3.4 委員會會得視計畫執行之狀況，必要時得改變原先所核定之免除受試者知情同意之決定。
IRB members may revoke the previous approval for the exemption of subject informed consent where applicable with respect to the actual study needs.

5.3.4 審查受試者監測之程序：
Review of procedures for subject surveillance

5.3.4.1 審查委員於審查時，須視風險之高低要求計畫主持人定期或不定期進行受試者之監測(包括監測之項目、時間、頻率及後續處置之措施)，以確保受試者之安全及權益。
In the review, IRB members shall request the principal investigator to monitor subjects periodically or non-periodically with respect to the risk level to ensure the safety, rights, and interests of subjects. Surveillance shall include the items, time, and frequency of monitoring and the measures for subsequent handling.

5.3.4.2 審議會得視計畫執行之狀況,必要時得改變原先所核定之受試者監測之程序。
IRB may request a change of the previously approved procedures for subject surveillance with respect to the status of project implementation.

5.3.4.3 調查受試者同意書取得過程之重點包括：
The foci of reviewing the collection process of ICFs of subjects include:

A. 是否依法取得受試對象/法定代理人的簽署
Check if the signature of the subject/legal proxy is obtained legally.

B. 解釋同意書的場所是否恰當
Check if the venue for explaining the ICF is appropriate.

C. 是否顧及潛在受試對象的隱私
Check if the privacy of potential subjects is considered.

D. 是否明確的說明此為研究，可以不參加
Check if subjects are informed of voluntary participation in the study.

E. 是否就同意書內容逐項做詳細的說明
Check if every detail of the ICF is explained.

F. 是否就受試對象提出的問題做詳細的答覆
Check if the questions asked by subjects are answered in detail.

G. 是否給予足夠的考慮時間
Check if subjects are given adequate time for consideration.

H. 受試對象是否在完全自主的情況下決定參與研究
Check if subjects are given absolute freedom for voluntary participation in the study.

5.3.5 審查受試者補助之程序：
Review of the procedures of subsidization for subjects

5.3.5.1 審查委員於審查時，應視計畫需要，評估受試者之風險利益，並審查給予研究對象之相關補助費用是否妥適，如車馬費、營養費...等。且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與受試者之書面資料。

In the review, IRB members shall evaluate the risks and benefits of subjects based on the study needs and review the fairness of allowances for subjects, such as travel expenses, nutrition fees, etc. In addition, the method, amount, and progress of disbursement of allowances for subjects shall be specified in the ICFs and other written documents for subjects.

5.3.5.2 審查委員於審查時，應審視如依研究所訂臨床試驗計畫，因而發生不良反應或傷害，其損害補償與保險之安排是否適當。
In a review, IRB members shall assess the fairness and suitability of the compensation and insurance arrangements for the aversive effects or injuries caused by the clinical trial of a study.

5.3.5.3 審查委員須審視受試者招募廣告之適當性，並確認招募廣告中無強調受試者將可獲得免費醫療或費用補助。
IRB members shall review the suitability of the recruitment advertisements and confirm that free medical treatment or subsidization are emphasized in such advertisements.

5.3.6 審查受試者招募之程序：審查委員依據「受試者招募指引」審查受試者招募的各種資料，包括平面廣告與多媒體，受試者收到的報酬、方式與時程，以確保招募方式的公平。
Review of the procedures for subject recruitment: IRB members shall review all data of subject recruitment with respect to the Subject Recruitment Guidelines, including graphics and multimedia advertisements and the remuneration, method and time of payment for subjects to ensure the fairness of recruitment.

5.3.7 受試者隱私保護及資料保密:審查委員於審查時須判斷計畫是否有適當的受試者的隱私保護及資料保密，應評估研究時收集的資料的敏感性,及研究者提供的保護是否足夠。
Privacy protection and information confidentiality of subjects: In the review, IRB members shall determine if the privacy and information of subjects are adequately protected in terms of the sensitiveness of data collected in the study period and the adequacy of protection offered by researchers.

5.5 文件歸檔：依標準作業程序（SOP 6.1）進行
Filing: Subject to SOP 6.1.

6. 附件 Attachment

6.1 附件一(KMUH/IRB/AF/2.1-01/11.0) 送審資料清單-新案(免審)
Attachment 1 (KMUH/IRB/AF/2.1-01/11.0) List of Files for Review - New Application (Waiver of Review)

6.2 附件二(KMUH/IRB/AF/2.1-02/11.0) 送審資料清單-新案(一般案)
Attachment 2 (KMUH/IRB/AF/2.1-02/11.0) List of Files for Review - New Application (General Case)

6.3 附件三(KMUH/IRB/AF/2.1-03/11.0) 送審資料清單-新案(簡審、基因相關與特殊及易受傷害族群)

Attachment 3 (KMUH/IRB/AF/2.1-03/11.0) List of Files for Review - New Application (Expedited Review, Gene, and Special/Vulnerable Population)

6.4 附件四(KMUH/IRB/AF/2.1-04/11.0) 送審資料清單-修正 (一般案、簡審、基因相關與特殊及易受傷害族群)
Attachment 4 (KMUH/IRB/AF/2.1-04/11.0) List of Files for Review – Amendment (General Case, Expedited Review, Gene-Related, and Special/Vulnerable Population)

6.5 附件五(KMUH/IRB/AF/2.1-05/11.0) 送審資料清單-期中報告(一般案、簡審、基因相關與特殊及易受傷害族群)
Attachment 5 (KMUH/IRB/AF/2.1-05/11.0) List of Files for Review – Interim Report (General Case, Expedited Review, Gene-Related, and Special/Vulnerable Population)

6.6 附件六(KMUH/IRB/AF/2.1-06/11.0) 送審資料清單-結案報告(一般案、簡審、基因相關與特殊及易受傷害族群)
Attachment 6 (KMUH/IRB/AF/2.1-06/11.0) List of Files for Review – Final Report (General Case, Expedited Review, Gene-Related, and Special/Vulnerable Population)

6.7 附件七(KMUH/IRB/AF/2.1-07/11.0) 送審資料清單-提前中止/提前終止(一般案、簡審、基因相關與特殊及易受傷害族群)
Attachment 7 (KMUH/IRB/AF/2.1-07/11.0) List of Files for Review – Early Discontinuance or Termination (General Case, Expedited Review, Gene-Related, and Special/Vulnerable Population)

6.8 附件八(KMUH/IRB/AF/2.1-08/11.0)原版受試者同意書
Attachment 8 (KMUH/IRB/AF/2.1-08/11.0) Original Informed consent Form

6.9 附件九(KMUH/IRB/AF/2.1-09/11.0)新醫療技術(含新醫療技術合併新醫療器材)臨床試驗受試者同意書
Attachment 9 (KMUH/IRB/AF/2.1-09/11.0) New Medical Technology (including new technology with new medical devices) Informed Consent Form for Trial Subjects

6.10 附件十(KMUH/IRB/AF/2.1-10/11.0)基因學研究之受檢者同意書
Attachment 10 (KMUH/IRB/AF/2.1-10/11.0) Informed Consent Form for Genetic Studies

6.11 附件十一(KMUH/IRB/AF/2.1-11/11.0)檢體或基因人體研究受檢者同意書
Attachment 11 (KMUH/IRB/AF/2.1-11/11.0) Samples or Genes Human Trial Informed Consent Form

6.12 附件十二(KMUH/IRB/AF/2.1-12/11.0)兒童版臨床研究/試驗受試者說明及同意書
Attachment 12 (KMUH/IRB/AF/2.1-12/11.0) Clinical Study for Minors/Descriptions and Informed Consent Form for Trial Subjects

6.13 附件十三(KMUH/IRB/AF/2.1-13/11.0)免除書面知情同意申請書
Attachment 13 (KMUH/IRB/AF/2.1-13/11.0) Application for Written Exemption of Informed Consent Form

6.14 附件十四(KMUH/IRB/AF/2.1-14/11.0)完全免除任何知情同意程序申請書
Attachment 14 (KMUH/IRB/AF/2.1-14/11.0) Application for Full Exemption of ICF Procedures

6.15 附件十五(KMUH/IRB/AF/2.1-15/11.0)匿名問卷研究受訪者知情同意說明書
Attachment 15 (KMUH/IRB/AF/2.1-15/11.0) Anonymous Survey Informed Consent Prospectus of Subjects

6.16 附件十六(KMUH/IRB/AF/2.1-16/11.0)問卷研究受訪者知情同意書
Attachment 16 (KMUH/IRB/AF/2.1-16/11.0) Survey Informed Consent Form of Subjects

6.17 附件十七(KMUH/IRB/AF/2.1-17/11.0)個人訓練時數統計表
Attachment 17 (KMUH/IRB/AF/2.1-17/11.0) Statistics on Personal Training Length

6.18 附件十八(KMUH/IRB/AF/2.1-18/11.0)檢體輸出擔保書
Attachment 18 (KMUH/IRB/AF/2.1-18/11.0) Sample Output Guarantee