



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

1. 目的 Purpose

財團法人高雄醫學大學附設中和紀念醫院人體試驗審查委員會（以下簡稱人委會）為獨立組織。對人體相關的試驗、研究計畫，提供獨立的審查、修正建議與監督，以確保受試者權利、安全與福祉。

The Institutional Review Board (IRB) of the Kaohsiung Medical University Chung-Ho Memorial Hospital is an independent organization that is responsible for reviewing and supervising all human research and trials, providing independent review, recommendation for amendments and supervision to protect the rights, safety and benefits of all test subjects.

2. 適用範圍 Scope

適用於本院人委會對人體相關研究計畫審查之一切運作。

This SOP applies to the operation of IRB on reviewing of human research protocols.

3. 參考文件 References

3.1 法規依據 Legislatures

3.1.1 醫療法第 78 條(2017 年 5 月)

Medical Care Act, Article 78 (May 2017)

3.1.2 人體試驗管理辦法(2016 年 4 月)

Regulations on Human Trials (April 2016)

3.1.3 人體研究法(2011 年 12 月)

Human Subjects Research Act (December 2011)

3.1.4 依「人體研究倫理審查委員會組織及運作管理辦法」(2012 年 8 月)

According to the “Regulations Governing the Organization and



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

Operational Management of the Institutional Review Board for Human Subject Research” (August 2012)

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

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

4.名詞定義 Terminology

4.1人體試驗委員會(Institutional Review Board, IRB): 依衛生福利部規定由具醫學背景之專業人員與非醫學背景之社會公正人士所共同組成，由正式成立之獨立運作委員會，執行審查、核准及監督人體研究案，以保護受試者之權利、安全與福祉。

Institutional Review Board (IRB): according to the regulations of the MOHW, the IRB is composed of professionals with medical backgrounds and other impartial experts of non-medical backgrounds. It is an official, independently operated committee that is in charge of reviewing, approving and supervising human research, and to protect the rights, safety and benefits of tests subjects.

4.2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 study: studies that are aimed to obtain, investigate, analyze or utilize information on human specimen, personal biological behaviors, physiology, psychology, genetic and medicine related information.

4.3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 specimen: materials of human origin, including cells, tissues, organs,



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

body fluids and other derivatives (including genetic material) from the human body (fetus and corpse included), and residual specimen.

4.4 臨床試驗：以發現或證明藥品在臨床、藥理或其他藥學上之作用為目的，而於人體執行之研究。

Clinical trials: any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmaceutical effects of an investigational product(s).

4.5 人體試驗：指新醫療技術、新藥品、新醫療器材及學名藥生體可用率、生體相等性之試驗研究。

Human trials: refers to experimental research of new medical technology, new medicament, new medical implement, or the bioavailability and bioequivalence of generic drugs conducted by medical care institutions on humans based on medical theory.

4.6 保密性：不得對未經授權的第三方洩露人委會的資料。

Confidentiality: data of the IRB cannot be disclosed to any unauthorized third parties.

4.7 科學專家：具有與審查的計畫案相關專業素養（含醫學或非醫學領域）的人員。

Scientific experts: personnel with professional expertise (including medical or non-medical fields) related to the protocols under review.

5. 作業內容 Scope of operation

5.1. 倫理基本原理

Basic ethical principles



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

5.1.1. 人委會依據赫爾辛基宣言(Declaration of Helsinki) 的精神及貝爾蒙報告(Belmont report)之倫理原則,尊重自主、行善及正義之原則,發表評論與建議而作成決定。

The IRB shall express opinions and comments and reach decisions based on the spirits of the Declaration of Helsinki, and the ethical principals of Belmont Report: Respect for person, Beneficent and Justice.

5.1.2. 人委會所通過計畫案須遵守衛生主管機關相關規定。

All protocols approved by the IRB shall adhere to regulations of the competent health authority agency.

5.1.3. 人委會在評估計畫案和倫理議題時,應明瞭不同國家可能有法律、文化、研究管理、醫療行為的多樣性。

When evaluating protocols and ethical issues, the IRB should be aware that different countries may have diverse legislation, cultures, research management and medical behaviors.

5.1.4. 人委會在審查計畫案時,應了解在不同的地域所提出的計畫案有不同的要求和條件。

When evaluating protocols, the IRB should be aware that protocols submitted in different regions may have different requirements and conditions.

5.1.5. 人委會應尋求國際性或國家性的倫理委員會的指導及認可。

The IRB should seek the guidance and approval from international or national research ethics committees.

5.1.6. 人委會需參考 WHO、國際醫藥法規協會(ICH)、衛生福利部公告之相關法令,來建立標準作業程序。



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

The IRB should refer to the legislatures of the WHO, ICH or the Ministry of Health and Welfare to develop standard operating procedures.

5.2 職責 Responsibilities

人委會之委員、工作人員應了解與遵守人體試驗/研究相關法規及人委會所制定之規範。

The committee members and staff members should understand and comply with the legislatures related to human trials/study and regulations of the IRB.

5.3 人委會的組成：Composition of IRB:

5.3.1 本院設立二個人委會，委員名單須陳報衛生福利部備查，並各自獨立行使業務。

The KMUH has two IRBs whose list must be submitted for reference by the MOHW; each IRB is individually responsible for its affairs.

5.3.2 每個人委會由委員 5 人以上組成，其中一人為主任委員、一人為副主任委員，一人為總幹事，執行秘書若干名，均由本院選任之。

Each IRB is composed of five or more members, one of which is the committee director, one deputy director, one director general and several executive secretaries; all of which are appointed by the KMUH.

5.3.3 人委會由具醫療科技背景之專業人員與非醫療科技背景之法律專家及其他社會公正人士組成。研究機構以外人士應達五分之二以上，且單一性別不得低於三分之一。

The IRB is composed of specialists with medical technology background, specialists without medical technology background (legal expert) and



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

other impartial experts. At least 2/5 of the members must be composed of external specialists, and the ratio of single gender may not exceed 1/3.

- 人委會委員組成不能只含單一專業領域。

The IRB cannot be composed of members from a single professional background.

- 至少一位委員負責科學層面審查。

At least one committee member is responsible for scientific review.

- 查驗登記研究案之審查委員，至少有一名為有執照之醫師。

Reviewers of registration studies must have at least one physician with practice license.

- 至少一位委員足以代表研究受試者之觀點。

At least one committee member should represent the perspective of the test subject.

5.3.4 諮詢專家：視需要邀請特定領域之專家擔任獨立諮詢人員。

Consulting expert: independent consultant with special backgrounds invited as required.

5.3.5 行政人員；由主任委員視需要配置足夠之專任人員，辦理人委會相關事務。

Administrative staff: specially appointed personnel by the committee director to handle the daily affairs of the IRB.

5.3.6 標準作業(SOP)修訂小組：由主任委員選派審查委員若干人，為任務編組。

SOP revision group: committee members appointed by the director and grouped according to tasks.



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

5.4. 委員/專家遴選資格與要求

Qualification and requirement for committee member/expert selection

5.4.1 公開遴選符合下列資格之儲備委員：

Reserve members with the following qualifications may be openly selected:

(A)大學以上學歷，具生物醫學、社工、法律、生物統計、基礎科學及倫理等專長或為受試者、社會公正人士、病友、消費者團體、宗教或民間團體代表等足以勝任受試者保護之任務。並具有高度熱忱者。

Those who holds a college degree or more, and have expertise in biomedical science, social work, law, biostatistics, basic science and ethics, or as a representative for test subjects, impartial experts, patient groups, consumer groups, religion or civil groups, and is competent for protection of test subjects, as well as high enthusiastic for the related tasks.

(B)具 GCP 或醫學倫理相關受訓證明。

Have GCP or medical ethics training certificate.

(C)不參與本院經營運作事務，包括研究副院長、研發長、產學長、業務發展單位人員等。

Not involved in the hospital's operational affairs, such as deputy superintendent of research, director of research and development, director of industry-academic collaboration, and personnel from business development units.



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

5.4.2 委員應由主任委員自儲備委員中提名，提報院長並核發聘書。任期為1年，連聘得連任之。

The committee members should be nominated by the director from the list of reserve committee members, and submitted to the superintendent for approval and issuing letters of employment. The term of service is 1 year and may be re-elected for re-appointment.

5.4.2.1 機構內委員係包含：人委會所屬機構之支薪或編制內人員(含留職停薪)、該機構之董監事、領有固定支薪或專任顧問及執業登記之人員。

Institutional members refer to the following: personnel on payroll or as staff of the IRB's parent organization (including those remained in position without pay), the board members of the organization, paid or specially appointed consultant, or personnel registered for practice license.

5.4.2.2 機構外委員：非人委會所屬機構之支薪或編制內人員，或屬同一機構，但沒有從屬關係之學校與附設醫院視為各自獨立單位，故學校之委員得屬機構外委員。非固定支薪之法律顧問也認定為機構外委員。

External members: personnel that are not on payroll or as staff of the IRB's parent organization, or from a school or affiliated hospital within the same organization that operates independently, and thus is not the subordinate of the said organization; legal consultants that are not on fixed payroll are also considered external members.



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

5.4.2.3 新聘任之委員應以觀察員身分參加人委會審查會議運作三個月，並閱讀執行秘書提供之相關資料。觀察期滿後方得執行審查工作。
Newly appointed members will join in the operation of the IRB as an observer for 3 months, and to study information provided by the executive secretary. The new members will partake in the IRB operation after the observation period has expired.

5.4.2.4 在計畫審查時，委員們必須以書面的方式申報和個人有關的利益衝突，包括財務、專業或其他方面。
During protocol reviews, committee members must declare in written form of any personal conflicts of interests, including financial, professional and other forms.

5.4.2.5 當委員申報利益衝突時，IRB 應根據「101年8月17日衛署醫字第 1010265129 號公告」決定利益衝突程度及處理方法。
The IRB should handle the conflicts of interests according to “Announcement Wei-Shu-Yi-Zi No. 1010265129 on August 17 of 2012” to determine the severity of conflicts and treatment methods.

5.4.2.6 在任期開始前，委員們需要簽署一份保密協議書。
Committee members are required to sign an agreement on confidentiality before the start of their terms of service.

5.4.3 諮詢專家得由主任委員自機構內外提名專業人士，針對一般及特殊族群，包括易受傷害族群(如未成年人、受刑人、原住民、孕婦、身心障礙、精神病患...等)、決定能力欠缺的受試者參與之案件、或有疑慮之案件，參與審查或提供諮詢意見。提報院長核發聘書。任期為 1 年，連聘得連任之。



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

The consulting expert shall be appointed by the director from nominated external members to participate or provide comments on the review of protocols containing, or suspected of containing, the following categories of subjects: special populations and vulnerable populations (including minors, inmates, aboriginals, pregnant women, mentally and physically disabled, and mental patients), as well as those who could not give consent of free will. The list of external members will be submitted to the superintendent for letters of employment; the term of service is 1 year, and may be re-elected for re-appointment.

5.5 行政人員聘任資格與要求

Employment qualification and criteria for administrative staff:

(A)大學以上學歷，且有高度熱忱者。

Has a college degree or more and highly enthusiastic

(B)具 GCP 或醫學倫理相關受訓證明。

Has GCP or medical ethics training certificate

(C)具備專業文書處理能力。

Has expertise in document processing

5.6 副主任委員/委員/諮詢專家/執行秘書/行政人員資格審查、聘任

Qualification review and employment of deputy director/committee member/consultant/executive secretary/administrative staff

5.6.1 主任委員進行聘任資格審查

The committee director conducts the qualification review

5.6.2 副主任委員/委員/專家/執行秘書由主任委員遴選推薦，院長聘任之(附件一)。



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

The nomination of the deputy director/committee member/expert/executive secretary is done by the committee director, and hired by the superintendent (Attachment 1).

5.6.3 行政人員由主任委員視編制需要而聘任之。

The administrative staff is required and hired by the committee director as needed.

5.7 委員/諮詢專家/執行秘書/行政人員職責

Responsibilities of the committee member/consultant/executive secretary/administrative staff

5.7.1 主任委員：負責主持會議並向機構的負責人報告會議結果，邀請獨立諮詢專家對計畫案提供專家意見。

Committee director: in charge of chairing the meetings and report the resolutions of the meeting to the organization's leader; invite independent consultants to comment on the protocols under review.

5.7.2 副主任委員：擔任主任委員職務代理人，於主任委員請假時代理主持會議。

Deputy director: act as the duty substitute of the committee director, and chairs the meeting during the director's leave of absence.

5.7.3 總幹事：檢查送審資料與追蹤審查時程，協助主任委員並執行交辦事項。

Director general: examines the protocol information and monitors the follow-up periods of the protocols; assists the committee director and carry out appointed tasks.

5.7.4 執行秘書：執行主任委員推動人委會相關事宜，臨床研究訓練課程之擬訂與執行計畫執行中之訪視、監測、稽核與查核。



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

Executive secretary: assists the director in promoting IRB affairs; plans clinical education training courses; implements the site visit, monitoring, auditing and inspection of the protocols in progress.

5.7.5 審查委員：每月固定參加人委會召開之會議，確保受試者權益與保護。

Reviewer: attends the monthly IRB meetings to maintain the protection of the test subject's rights and safety

(A) 於限期內完成臨床試驗計畫初審案、複審案，以及變更案、延長試驗案、持續審查案、緊急案、結案報告等審查。

Completes the following reviews within time limits: initial review of the clinical trial, re-submission, alteration, expansion, continuous review, emergency cases and summary reports.

(B) 審查不良事件/未預期事件、不遵從案件及追蹤後續發展。

Review adverse events/unexpected events, non-compliances and follow-up on subsequent development.

(C) 協助審查檢討與制訂制度和政策。

Assists in the examination and development of policies and system measures.

(D) 完成 GCP 及相關醫學倫理受訓時數要求。

Complete the training hour requirement for GCP and medical ethics.

5.7.6 諮詢專家：到會議現場或以書面陳述意見。

Consultant: delivers comments on site or via written form.

5.7.7 行政人員；有效率的執行下列工作

Administrative staff: efficiently performs the following tasks



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

(A) 文件登錄編碼、輸入日期與送審。

Registering documents, date input and sent for review.

(B) 彙整審查意見並傳送回覆資料

Compiles reviewer's comments and deliver responses.

(C) 檢查送審資料與追蹤審查時程。

Examines the information submitted and follow on the review time schedule.

(D) 協助函辦會議議程與進行，並保存會議記錄三年。

Notifying meeting agenda and progression, and keep the meeting minutes for at least 3 years.

(E) 相關資料建檔、存檔。

Filing and archiving of related information.

(F) 新藥登錄計畫與嚴重不良事件之通報衛生福利部。

Register new drugs and notify the MOHW of any SAEs.

(G) 執行例行性行政庶務及交辦事項。

Perform routine administrative tasks and additional work.

(H) 完成 GCP 及相關醫學倫理受訓時數要求。

Completes the training hour requirement of GCP and medical ethics.

5.7.8 標準作業(SOP)修訂小組：

SOP revision group:

(A) 定期修訂標準作業程序相關事務。

Carry out regular SOP revisions.

(B) 提議所需的標準作業程序，並撰寫草案。

Propose SOPs and develop drafts.



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

(C) 提交草案經人委會確認後陳核院方，立即公告。

Submit the drafts to the IRB and for approval by the hospital management, and to announce the drafts.

5.8 辭職、解聘與替補 Resignation, dismissal and replacement

5.8.4 辭職：

Resignation:

5.8.4.1 任期內之委員/總幹事/執行秘書/諮詢專家請辭時，應以書面方式向主任委員遞出「人體試驗審查委員會辭職書」(附件)。請辭後不得參與人委會任何事務。

Committee member/director general/executive secretary/consultant that intends to resign during the term of service shall submit the “IRB Resignation Form” (Attachment) in writing to the director, and should not participate in further IRB affairs after resignation.

5.8.4.2 主任委員收到正式辭職書後，須自儲備委員名單中提名，陳請院長聘任之。

After receiving official letter of resignation, the director shall nominate a new person from the reserve list and submit for employment by the superintendent.

5.9.5 解聘：

Dismissal:

5.9.5.1 下列情形之一者，主任委員應立即解聘委員/諮詢專家/執行秘書/總幹事：

The committee director may immediately dismiss any committee



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

member/consultant/executive secretary/directore general during any of the following situations:

(A)違反國內外相關法規或本會相關政策。

Violation of the domestic or international legislatures or the IRB policy

(B)因其疏忽導致本會無法正常運作或名譽受損。

Abnormal operation of the IRB or reputation damage due to negligence

5.9.5.2 下列情形之一者，主任委員得解聘委員/審查專家/執行秘書/總幹事：

The committee director may dismiss any committee member/consultant/executive secretary/director general during any of the following situations:

(A)任期內累計無故缺席三次以上或未出席超過應出席次數三分之一以上。

Absence without cause for more than three times during the term of service or missed required attendance by more than 1/3.

(B)因可歸責事件導致負責審查案件超過審查期限，年累計三次以上。

Accumulate more than three cases per year that have exceeded the review period due to attributable causes.

(C)嚴重違反利益迴避原則。

Serious violation of the principles of conflicts of interests.



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

5.9.5.3 委員/審查專家/執行秘書解聘需以書面告知。

Dismissals of committee member/reviewer/executive secretary are delivered via written notifications.

5.9.6 替補

Replacement

5.9.6.1 委員/審查專家/執行秘書出缺時，由主任委員提名經院長同意聘任替補。

Vacancy of committee member/reviewer/executive secretary shall be nominated by the committee director and appointed by the superintendent.

5.9.6.2 當委員辭職或解聘時，經主任委員提名替補，其聘期至原聘委員聘期屆滿之日為止。

When a committee member is dismissed or leaves the position, the committee director will propose nominees; the terms of service will be until the end of the terms of the original committee member.

5.9.7 評核

Evaluation

5.9.7.1 主任委員就副主任委員/委員/總幹事/執行秘書/行政人員效率、出席率進行評核，每年評核一次。行政人員將於每年11月統計各項評核資料，由主任委員進行評核，並做為聘任之依據，評核結果將書面回饋給受評人員。受評人員收到書面評核，需簽名確認後送回本人委會。

The director conducts evaluation of the deputy director/committee member/director general/executive secretary/administrative staff on



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

efficiency and attendance rate annually. The administrative staff will tally all evaluation data in the November of each year and send for evaluation by the director, who will use the data as basis for re-appointment. The results of the evaluation will be return to the evaluated person in written form. After receiving the written evaluation, the person must sign to verify and return to the IRB.

5.9.7.2 主任委員自評(附件三)後，由審查委員不記名評核。

Self-evaluation of the committee director (Attachment 3) is anonymously evaluated by the reviewer.

5.9.7.3 委員依以下評核項目，作為遴聘參考(附件五)：

Committee member will be evaluated on the following as basis for nomination (Attachment 5):

(A) 會議出席率(會議出席次數)、主持會議次數或審查頻率、審查會議會前之準備程度。

Meeting attendance rate (meeting attendances), meeting chairing or review frequency, preparation before review meeting

(B) 審查效率：包括審查天數、簡易或一般審查案件數。

Efficiency of review: including review days and number of expedited or general reviews.

(C) 審查品質：審查正確性及專業性，包括與計畫主持人的溝通與協助主持人的能力、審查意見與會議決議意見之吻合度。

Quality of review: accuracy and professionalism of reviews, including communication with the principal investigator, ability



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

to assist investigator, and consistency between review comments and meeting resolutions.

(D) 對法規及本院政策與 SOP 的認識

Awareness of legislatures and hospital policies and SOP

(E) 溝通與合作之能力

Ability to communicate and collaborate

(F) 教育訓練時數

Education training hours

5.9.7.4 副主任委員/總幹事/執行秘書(附件四)

Deputy director/director general/executive secretary (Attachment 4)

(A) 工作品質及工作效率

Work quality and efficiency

(B) 對法規及本院政策與 SOP 的認識

Awareness of legislatures and hospital policies and SOP

(C) 專案改善能力

Ability for project improvement

(D) 主任委員交辦事項完成率

Completion of tasks assigned by the committee director

5.9.7.5 行政人員(附件六)

Administrative staff (Attachment 6)

(A) 工作品質；行政審查確實性、行政審查審查時效率。

Work quality: credibility and time efficiency of administrative review.



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

(B) 對法規及本院政策與 SOP 的認識

Awareness of legislatures and hospital policies and SOP.

(C) 與執行秘書溝通與共同工作之能力

Ability to cooperate and communicate with the executive secretary.

(D) 交辦事項完成率

Completion of assigned tasks.

(E) 參與評鑑及承辦教育訓練活動之能力與態度

Ability and attitude in participating accreditation and organizing education training activities.

(F) 教育訓練時數

Education training hours.

5.10 審查費及車馬費

Review fee and transportation fee

5.4.1 委員與審查專家之案件審查應給予審查費用。(參考本會之審查費/車馬費給付標準)

Review fee should be given to members participating in protocol reviews (please refer to the payment standards on review fee/transportation fee)

5.4.2 外聘委員及受試者代表(非委員)依規定按次給予車馬費。(參考本會之審查費/車馬費給付標準)

External members and subject representatives (non-committee member) shall be provided with transportation fees based on number of review participation (please refer to the payment standards on review fee/transportation fee).



高雄醫學大學附設中和紀念醫院

Kaohsiung Medical University Chung-Ho Memorial Hospital

文件編碼 Document code	1.3	檔案名稱 File name	人體試驗審查委員會的組成 The Composition of Institutional Review Board		
公告日期 Announcement date	2018年1月1日 January 1, 2018	執行日期 Implementation date	2018年1月1日 January 1, 2018	版次 Version	11版 Ver. 11

6.附件 Attachment

6.1附件一(KMUH/IRB/AF/1.3-01/11.0)人體試驗委員會委員聘書與聘任通知

Attachment 1 (KMUH/IRB/AF/1.3-01/11.0) IRB Letter of Employment and Notice for Employed Committee Member

6.2附件二(KMUH/IRB/AF/1.3-02/11.0)人體試驗審查委員會辭職書

Attachment 2 (KMUH/IRB/AF/1.3-02/11.0) IRB Resignation Form

6.3附件三(KMUH/IRB/AF/1.3-03/11.0)主任委員評量表

Attachment 3 (KMUH/IRB/AF/1.3-03/11.0) Committee Director Evaluation Form

6.4附件四(KMUH/IRB/AF/1.3-04/11.0)副主任委員/總幹事/執行秘書評量表

Attachment 4 (KMUH/IRB/AF/1.3-04/11.0) Deputy Committee Director/Director General/Executive Secretary Evaluation Form

6.5附件五(KMUH/IRB/AF/1.3-05/11.0)審查委員評量表

Attachment 5 (KMUH/IRB/AF/1.3-05/11.0) Reviewers Evaluation Form

6.6附件六(KMUH/IRB/AF/1.3-06/11.0)行政人員評量表

Attachment 6 (KMUH/IRB/AF/1.3-06/11.0) Administrative Staff Evaluation Form