1.目的 Purpose

提供申請計畫免審之程序及人委會審查管理的依據。

To instruct on the procedures for study protocol review exemption and provides a basis for management by the IRB.

2. 適用範圍 Scope

執行人體研究，研究案件非以未成年人、收容人、原住民、孕婦、身心障礙、精神病患、判斷受不當脅迫或無法以自由意願做決定者為研究對象，具有必要符合項目且符合下列可選符合項目情形之一，得免委員會審查，並由委員會核發免審證明：

Human research and studies that do not include the following as subjects: minors, inmates, aboriginals, pregnant women, mentally and physically disabled, mental patients, and persons that have been coerced, forced or did not given free consent, and have fulfilled all required conditions and fulfilled at least (1) one of the following optional criteria, is eligible for exemption of review by the IRB, and will be issued a certificate of review exemption by the IRB:

2.1 必要符合項目：研究計畫屬最低風險，係指研究對象所遭受之危害或不適的機率或強度，不高於日常生活中遭受的危害或不適，且其研究對象所遭受之風險不高於未參加該研究者。

Required criteria: the research/study is of the minimal risk category, which means that the probability or intensity of the hazards or discomforts encountered by the test subjects are not higher than the hazards or discomforts encountered in normal daily life. Additionally, the risks encountered by the tests subjects are not higher than those not participating in the study

2.2可選符合項目：

Optional criteria:

2.2.1 於公開場合進行之非記名、非互動且非介入性之研究，且無從自蒐集之資訊辨識特定之個人。

Studies that are conducted openly, anonymously, non-interactive and non-intervention, and could not identify specific individual with the information collected.

2.2.2 使用已合法公開週知之資訊，且資訊之使用符合其公開週知之目的。

Studies that use authorized and openly disclosed information, and the usage of such information complies with the rules on open information.

2.2.3 公務機關執行法定職務，自行或委託專業機構進行之公共政策成效評估研究。

Public service agency conducting its statutory duties; conducting or commissioning professional institutions to implement evaluation on the effectiveness of public policies.

2.2.4 於一般教學環境中進行之教育評量或測試、教學技巧或成效評估之研究。

Anonymous or blind (unable to obtain identity from information obtained) implementation of education evaluation or testing in normal teaching environment, assessment of teaching skills and outcomes.

3.參考文件 References

3.1 人體研究法(2011年12月)

Human Subjects Research Act (December 2011)

3.2 個人資料保護法(2010年5月)

Personal Information Protection Act (May 2010)

3.3 人體生物資料庫管理條例(2011年1月)

Human Biobank Management Act (January 2011)

3.4 得免倫理審查委員會審查之人體研究案件範圍(2012 年 7 月)

Scope of human clinical trials exempted from review by the research ethics committees (July 2012)

3.5 美國衛生福利部Department of Health and Human Service(DHHS)之美國聯邦法規Common Federal Rule(CFR)，第45章，第46部分，受試者保護。

Section 46 on protection of test subjects in Chapter 45 of the common Federal Rule (CFR) of the United States Department of Health and Human Service (DHHS).

3.6赫爾辛基宣言(2013年)

Helsinki Declaration (2013)

4.名詞定義 Terminology

4.1 免予審查：適用於審查不超過微小風險及最低風險的研究，符合「得免倫理審查委員會審查之人體研究案件範圍」。

Review exemption: applicable for review of studies that do not exceed minimal and lowest risks, and comply with the Scope of human clinical trials exempted from review by the research ethics committees.

4.2 微小風險： 對身體或生理上造成的傷害的機會或程度，相當於建康者的日常生活、常規醫學及心理學檢查所造成者,並沒有因為參與計畫而增加。

Low 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.

4.3 最低風險：指研究對象所遭受之危害或不適的機率或強度、不高於日常生活中遭受的危害或不適。

Minimal risk: the probability or intensity of the hazards or discomforts encountered by the test subjects are not higher than the hazards or discomforts encountered in normal daily life.

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
行政審查 Administrative review	行政秘書 Administrative Secretary	確認以下送審文件完整 Check the following documents are complete 清單 Check list 計畫申請書 Protocol application 個人資料表（CV） Curriculum Vitate 個人訓練時數統計表及證明文件 Personal training hours and certificate documents 繳費收據影本 Copy of fee invoice
分案審查 Case review	執行秘書 Executive secretary	分案表 Distribution form
委員審查 Committee member review	委員 Committee member	人體試驗/研究免審計畫案委員核定表 Committee member check list on review exemption for human research/study protocols
主任委員核定 Approval by	主任委員 Committee director	無 NA

committee director		
審查會議備查 Future reference by the IRB meeting	審查會議委員 Member of review meeting	無 NA

5.2職責

Responsibilities

5.2.1 計畫主持人：需自評符合免審範圍，但無權決定自己的研究可以符合免審，於研究進行前必須向人委會提出免審申請，並檢附相關文件。經由人委會審查通過後，始得進行研究。

Principal investigator: performs self-evaluation to confirm that the study fulfills the scope for review exemption, but cannot signally decide that the study is exempted from review. The principal investigator must apply with the IRB for review exemption before the study commences, and to supply additional documents for the IRB to review.

5.2.2 行政人員：負責送審文件之行政程序審查，確認文件齊全，格式正確，及團隊人員訓練時數符合規範。

Administrative staff: responsible for the administrative review of the documents and verify that the documents are complete and of the correct format, and the training hours of the research team are inline with the regulations.

5.2.3 執行祕書：進行分案。

Executive secretary: distribute the protocols

5.2.4 審查委員/專家：負責計畫案之審查。

Reviewer/specialist: responsible for the review of the protocols

5.2.5 主任委員：負責計畫案之核定。

Committee director: responsible for approval of the protocols

5.3細則 Rules

5.3.1 受理送審計畫案

Acceptance of the protocol review application

5.3.1.1 計畫主持人依「人體試驗/研究免審計畫案送審文件清單」進行申請。

The PI applies for review according to the check list on documents for review exemption of human research/study protocols

5.3.1.2 行政審查完備性

Integrity of administrative review

A.行政人員核對送審資料內容是否完備。送審資料應包括：(A)人體試驗/研究免審計畫案送審文件清單。(B)人體試驗/研究免審計畫案申請書。(C)計畫主持人、共同主持人、協同主持人個人資料表（CV）。(D)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文件。

The administrative staff verifies that the review application is complete, which should include the following: (A) Check list on documents for review exemption of human research/study protocols, (B) Application for review exemption of human research/study protocols, (C) Curriculum Vitate (CVs) of the principal investigator, co-investigator and sub-investigator, (D) Documentation on the human research training programs in the previous three (3) years for the principal investigator, co-investigator and sub-investigator.

B.送審文件內容若有缺漏應請計畫主持人補齊資料。

The principal investigator is required to submit information that are missing from the review application.

5.3.2 計畫案分案

Protocol distribution

5.3.2.1 執行祕書須分案給一位審查委員/專家,分案時限為二個工作日。

The executive secretary will distribute the protocol to a reviewer/specialist. The time limit for protocol distribution is two (2) working days.

5.3.2.2 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。

The reviewer must verify whether conflicts of interests applies before reviewing the case; if yes, the executive secretary will distribute the protocol to another reviewer.

5.3.2.3 審查委員/專家接獲通知須於二個工作日內回覆是否同意審查，未回覆視同不同意，執行秘書須重新分案。

Upon receiving the notification, the reviewer/specialist must reply within two (2) working days on whether to proceed with the review. A no reply constitutes disagreement, and the executive secretary will distribute the case to another reviewer.

5.3.3 計畫案審查

Protocol review

5.3.3.1 審查委員/專家審查時限為七個工作日

The time limit for review by reviewer/specialist is seven (7) working days.

5.3.3.2 審查委員/專家依「人體試驗/研究免審計畫案委員核定表」進行審查

The review by reviewer/specialist will follow the committee member check list on review exemption for human research/study protocols

5.3.3.3 審查重點

Review keypoints

A.此研究是否符合為免審範圍？

Does the protocol fulfill the scope for review exemption?

B.此研究是否不超過微小風險及最低風險？

Does the protocol exceed minimal and lowest risks?

C.此研究是否符合倫理原則？

Does the protocol fulfill the ethical principles?

D.可辨識受試者資料，是否有完善的保密措施？

Is the subject's identity properly protected in the protocol?

E.是否有確保個人隱私？

Is the subjects' personal privacy guaranteed?

F.是否有公平的選擇受試者？

Are subjects fairly recruited?

G.計畫是否與受試者有互動過程？

Does the protocol feature interaction with the subjects?

5.3.4 審查結果 Results of review

5.3.4.1不符合免予審查條件，予以「不通過」應提供具體原因並建議審查方式，通知計畫主持人。告知不符合之原因及改成簡易審查或一般審查之送審程序。

Protocols that do not qualify for review exemption will be rejected by the reviewer. The reasons for rejection and the recommendation for improvement should be given to the principal investigator. The reasons for rejection should be provided along with suggestion to change to expedited review or general review.

5.3.4.2 符合免予審查條件，送主委核定後列入審查會議備查。

Protocols fulfilling the criteria for review exemption will be approved by the committee director and included for future references by the IRB meeting.

5.3.4.3 若核定審查結果為「不通過」,而計畫主持人對審查結果有疑 異，可向人委會申訴，列入審查會議討論。

If the principal investigator has doubts on receiving rejection from the protocol review, he/she may appeal to the IRB, and the protocol in question will be discussed during the IRB meetings.

5.3.5 審查會議備查通過，符合免予審查條件，於五個工作日內出具「人體試驗 /研究同意免審證明書」。

Once the protocol has passed the review and qualifies for review exemption, a certificate of review exemption for human research/study will be issued within five (5) working days.

5.3.6 免審計畫案無須繳交期中及結案報告，惟計畫執行期間若發生屬非預期、相關及涉及造成受試者或他人更大傷害風險之非預期問題，須向本會通報。若計畫擬進行變更且超過原免審範圍，計畫人主持人須重新以新案送審。

Protocols that are review exempted do not need to submit interim and completion report; however, if any unexpected issues occurred during the study period that have caused the test subjects or others greater risks of injury and damage, the incidents must be reported to the IRB. If the protocol is to undergo alterations and the scope of alterations have exceeded the original scope for review exemption, the principal investigator must re-submit the protocol as a new case.

5.3.7 審查文件保存至預定計畫結束期限後三年。

The review documents will be kept for three (3) years after the planned completion of the study period.

6.附件 Attachment

6.1 附件一 (KMUH/IRB/AF/2.5-01/11.0) 人體試驗/研究免審計畫案送審文件清單

Attachment 1 (KMUH/IRB/AF/2.5-01/11.0) Check list on Documents for Review Exemption of Human trial/study protocols

6.2 附件二 (KMUH/IRB/AF/2.5-02/11.0) 人體試驗/研究免審計畫案申請書

Attachment 2 (KMUH/IRB/AF/2.5-02/11.0) Application Form for Review Exemption of Human Trial/Study

6.3 附件三 (KMUH/IRB/AF/2.5-03/11.0) 人體試驗(研究)免審計畫案委員核定表

Attachment 3 (KMUH/IRB/AF/2.5-03/11.0) Committee Member Check List on Review Exemption for Human Trial/Study

6.4 附件四 (KMUH/IRB/AF/2.5-04/11.0) 人體試驗同意免審證明書

Attachment 4 (KMUH/IRB/AF/2.5-04/11.0) Exempt Trials Approval Certificate of Human Study

6.5 附件五 (KMUH/IRB/AF/2.5-05/11.0) 個人訓練時數統計表

Attachment 5 (KMUH/IRB/AF/2.5-05/11.0) Personal Training Hour Record

6.6 附件六 (KMUH/IRB/AF/2.5-06/11.0) 臨床研究人員利益衝突宣告揭露聲明書

Attachment 6 (KMUH/IRB/AF/2.5-06/11.0) Declaration of the Conflicts of Interests by the Clinical Study Researcher