1.目的 Purpose

提供計劃案申請免除或改變知情同意審查原則，以保護受試者福祉與權益。

To provide the rules of reviewing study protocols applying for waivers or alternations of informed consent, in order to protect the welfare and rights of the subjects.

2. 適用範圍 Scope

2.1 人委會審查案件，若未涉及暴露研究參與者隱私之敏感性議題，或無法確認檢體提供者之情況，可適用於免除或改變知情同意。

During IRB reviewing the cases, if the study does not involve insensitive topics such as breaching the privacy of the study participants, or situations that the status of the sample providers cannot be confirmed, waiver or alternation of informed consent is applicable to the study.

2.2 涉及敏感議題之研究，若簽署同意書是唯一暴露受試者隱私之途徑，可適用於改變知情同意。

For studies involving in sensitive topics, if signing the consent form is the only route to breach the privacy of the subject, the amendment to informed consent is applicable.

3.參考文件 References

3.1人體研究法 第12條 (2011年12月)

Human Subject Research Act, Article 12(December 2011)

3.2得免取得研究對象同意之人體研究案件範圍 (2012年7月)

The Scope of Human Trials Applicable to Subject Consent Waiver (July 2012)

3.3 AAHRPP Domain II.3.G

3.4 FDA：CFR 46

4.名詞定義 Terminology

4.1免除知情同意：免除受試者同意書，且得不告知受試者研究相關資訊。

Waiver informed consent: The subject informed consent form is waived and study-related information could be not informed the subjects.

4.2改變知情同意：免除簽署書面受試者同意書，但需以其他方式告知受試者研究相關資訊。

Alteration of informed consent: The subject's informed consent form is waived, but the subjects shall be informed of study-related information by other ways.

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
送交申請資料 Submit the application	申請人 Applicant	免除/改變知情同意申請書 Waiver/Alteration of informed consent
確認送審文件完備 Check whether submitted files completely	行政人員 Administrative Staff	送審資料 Files for review
審查 Review	審查委員/專家 Reviewer/Expert	送審資料 Files for review
決議 Resolution	審查會議 Reviewer meeting	審查意見表 Review comments form 送審資料 Files for review
通知決議結果 文件歸檔 Notify the resolution Archive the files	行政人員 Administrative Staff	送審資料/審查意見表/會議記錄 Review comments form/Review comments form/Meeting minutes

5.2職責Responsibilities

5.2.1 計畫主持人：應於申請免除或改變知情同意計畫案中說明原因，並填寫免除或改變知情同意申請書

The Principal Investigator (PI): shall describe reasons of waiver or alteration of informed consent in the study protocol and fill in the application form for waiver or alteration of informed consent.

5.2.2 審查委員及審查專家：依免除或改變知情同意申請書及計畫案內容，於期限內完成審查是否符合免除或改變知情同意之規範。

Reviewers and review experts: will complete reviewing within time limit

whether the study has met the requirements for waiver or alteration of informed consent based on the contents of the application form and the study protocol.

5.2.3 審查會議: 依審查委員及審查專家審查意見及計畫內容，決議計畫案是否可免除或改變知情同意。

Reviewer meeting: will decide whether the study can waive or alter informed consent based on the reviewers' and experts' review comments and study protocol.

5.2.3 行政人員：負責受理申請案件、文件歸檔以及會後審查決議通知計畫主持人。

Administrative staff: are responsible for receiving applications, archiving files and informing PI after the review resolution has been made.

5.3 流程 Process

5.3.1 得免除或改變知情同意審查程序

Review procedures for waiver or alteration of informed consent

5.3.1.1 簽署受試者同意書應為必要，若事先合理預期無法取得知情同意，或取得知情同意會增加受試者風險，由主持人提出申請，經人委會核准得免除或改變知情同意後發給同意證明書。

The signature of subject consent form shall be mandatory. If the acquisition of the informed consent is reasonably expected to fail in advance, or the acquisition of informed consent will increase subject risks, after submitting the application by the PI, the IRB will approve and issue a certificate of approval for waiver or alteration of informed consent.

5.3.1.2 若人委會未核准，需補附受試者同意書送審。

If the IRB hasn't approved, subject informed consent form shall be supplied for review.

5.3.1.3 准予免除或改變知情同意之研究,計畫主持人仍應盡可能尊重受試者之自主權。

Studies that are approved for waiver or alteration of informed consent, the PI still need to respect the autonomy of the subjects as much as possible.

5.3.1.4 計畫執行過程，計畫內容變更或面臨之風險變更後，人委會將重新進行是否可繼續免除或改變知情同意之評估。

During study implementation, the IRB will re-evaluate the continuance of waiver or alteration of informed consent after protocol or risk level amendments.

5.3.2 審查研究計畫得免除或改變知情同意範疇

The study is within the scope of waiver or alteration of informed consent

5.3.2.1 改變知情同意

Alteration of informed consent

A.依照研究性質，取得受試者之書面知情同意反而對受試者不利。

According to the study nature, the acquisition of written subject informed cornet will cause disadvantage effects on the subjects.

B.需在計畫書中說明告知受試者研究資訊的方式，並依計畫書內容執行告知程序。

Study information shall be described in the study protocol for the

subjects to understand, and the informed procedures shall be performed in accordance with the study protocol.

5.3.2.2 免除知情同意

Waiver of informed consent

A.研究計畫屬於最低風險，對研究對象之可能風險不超過未參與研究者，不免除事先取得研究對象同意則無法進行，且不影響研究對象之權益。

The study has minimal risks and the potential risk level to the study subjects do not beyond the level of non-participants. However, the study cannot be implemented without obtaining the consents from study subjects in advance, but the rights of the study subjects are not affected.

(A)如有必要，受試族群於研究進行期間及研究結束後，在適當的情況下會提供受試族群相關的資訊。

If necessary, subject population-related information will be provided under proper circumstances during and after the study.

(B)某些狀況容許免除未成年受試者的父母同意，例如：受虐童...等等。

Some situations allow waiver of consent from minor subject's parents, including abused children, etc.

B.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，且研究屬最低風險。

The self-conducted or commissioned professional

institute-conducted studies involving public policy assessment for public affair institutes to perform legal tasks have minimal risks.

C.自合法生物資料庫取得之去連結或無法辨識特定個人資料、檔案、文件、資訊或檢體進行研究。但不包括涉及族群或群體利益者。

Use the delinked or unrecognizable personal data, files, documents, information or samples derived from legal biologic database for studies, but studies involving population or group interests are not included.

(A)請清楚寫明取得資料、檔案、文件、資訊或檢體之方法與過程。

Please clearly describe the methods and process of obtaining data, files, documents, information or samples.

6.附件 Attachment

6.1附件一(KMUH/IRB/AF/2.6-01/11.0)改變知情同意申請書

Attachment 1 (KMUH/IRB/AF/2.6-01/11.0) Alternation of Informed Consent Form

6.2附件二(KMUH/IRB/AF/2.6-02/11.0)免除知情同意申請書

Attachment 2 (KMUH/IRB/AF/2.6-02/11.0) Waiver of Informed Consent Form