1.目的 Purpose

本標準作業程序訂定目的為提供保密與利益衝突管理原則,作為相關人員行為準則。

The purpose of this standard operating procedure is to provide principles on the management of confidentiality and conflicts of interests and is intended to act as guidelines on personal behaviors.

2. 適用範圍 Scope

2.1本標準作業程序明訂簽署及保存的細節，包括參與人委會之相關人員所須遵從之保密及利益衝突之範圍及作業流程。

This standard operating procedure describe the details on contract signing and keeping, including the scope of confidentiality and conflicts of interests that must be complied by the personnel participating in the IRB.

2.2本標準作業程序適用於參與人委會之相關人員，包含委員、諮詢專家、執行秘書、行政人員、觀摩/列席審查會議及參訪、或主管機關查訪之人員、諮詢專家等，皆有責任去閱讀、了解、接受和簽署保密利益衝突與迴避協議書。

This operating procedure is applicable to all personnel participating in the IRB, including committee member, executive secretary, administrative staff, observer of the meetings/site visits, inspection personnel from the competent authority agency and consulting experts. Said personnel are responsible to read, understand, accept and sign the accords for confidentiality and conflicts of interests.

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人體試驗管理辦法 (2016年4月)

Regulations on Human Trials (April 2016)

3.3藥品優良臨床試驗準則（2010年7月）

Regulations for Good Clinical Practice (July 2010)

3.4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)

3.5醫療器材優良臨床試驗作業規範 (2016年1月)

Regulations for Good Clinical Practice on Medical Device (January 2016)

3.6 AAHRPP 美國臨床研究受試者保護 評鑑基準(2015年1月)

Accreditation of Human Research Protection Program, United States (January 2015)

4.名詞定義 Terminology

4.1隱私：指個人能自主控制提供自己的個人、身體、行為或認知等各方面的資訊給他人的程度,包括的分享時的時機及環境。

Privacy: the level of control an individual can exert on sharing of his/her own personal information, body, behaviors or cognition with others, including the timing and environment of information sharing.

4.2保密：講的是「資料」，是指維持研究者與受試者之間有關如何處理、取用及散播可辨識受試者身分的個人資料。非經授權不得任意公佈資訊。

Confidentiality: is about the “data”, refer to how the researcher and subjects agree on the disposal, usage and distribution of personal identity data, which may not be publicly disclosed without authorization.

4.3保密利益協議：有時稱為秘密或不公開協議。這協議是用來保護交易的秘密、資訊和專業，使其他學習者不致於濫用。任何類型的資訊在協議下都可被保密，但大部分的保密協議都有排除範圍，當事者可以使用何種保密資料，必須包含在保密協議內。協議必須設立時段，在某段期間內須維持資料的保密性，過此時段資料將會公開。

Confidentiality agreement: agreement that protects the secrets, information and expertise involved in a transaction, so that others may not exploit such information. Any type of information may be kept confidential under the agreement, but most confidential agreement has a range of exclusion. The type of confidential data available to the parties involved must be specified in the confidential agreement. The agreement must agree upon a period of time where the data will remain confidential within the specified period; after the period has expired, the data can be disclosed publicly.

4.4利益衝突(COI)：指相關人員執行職務時，因其作為或不作為，直接或間接使本人或其關係人獲取利益者。

Conflicts of interests: refers to any actions or inactions from related personnel on duty that have directly or indirectly resulted in gaining of interests for themselves or other related parties.

4.5利益：不僅限於財務利益，包括專利、授權等。財務利益可能係源自授權所衍生之授權收益、新創公司自學校取得技術授權（通常係專屬授權）所生之股份利益，甚至係大學所創設之創投資金對其衍生公司所挹注之資金，產業界提供回饋金、研究設備、資助研究。

Interests: not limited to financial profits, such as patents and authorizations. Financial interests may be generate from profits gained from granting of authorization, share profits gained by start-up companies from obtaining technology license from schools (exclusive license), capital generated by

venture capital fund invested by universities in spin-off companies, commissions, research equipment and funding provided by the industry.

4.6財務之利益衝突

Financial Conflicts of Interests

4.6.1委員或其配偶與未成年子女於過去十二個月期間，自該臨床研究委託者所收受之報酬(如顧問費、演講費、出席費等)、捐贈、禮品及其他具金錢價值之給付，合計達十五萬元以上者。(參考NIH/FDA規定)

The total value of remunerations (e.g. consultant fees, gratuities and attendance feeds), donations, gifts and payment of monetary values received by the committee members, their spouses and minor children in the past 12 months have amounted to NT$150,000 or more (referred to NIH/FDA regulations)

4.6.2委員或其配偶與未成年子女於過去十二個月期間，對該臨床研究計畫委託者之資產持股利益(如股份、股票選擇權等)達資本額5%以上者。(參考NIH/FDA規定)

The total value of the clinical trial generated share holder profits (e.g. shares, stock options) received by the committee members, their spouses and minor children have amounted to 5% or more of the capital value (referred to NIH/FDA regulations).

4.6.3委員或其配偶與未成年子女為該臨床研究所使用之專利或著作之所有權人或對該臨床研究所使用之專利或著作獲有授權金。

The committee member, their spouses or minor children are the owner of the patents or publications used by the clinical study, or receive loyalties from the patents or publications used by the clinical study.

4.6.4委員或其配偶與未成年子女自該臨床研究計畫委託者所收受之報酬數值可能受該計畫成果之影響。

The value of remuneration received by the committee member, their spouses or minor children from the study sponsor may be affected by the results of the study.

4.6.5委員或其配偶與未成年子女為該臨床研究計畫委託者之員工、支薪之顧問或董事。

The committee member, their spouses and minor children are employees, paid consultants or board members of the study sponsor.

4.7非財務之利益衝突

Non-Financial Conflict of Interest

4.7.1委員擔任該臨床研究計畫之主要主持人、共同主持人、協同主持人，或參與該臨床研究計畫之執行。

The IRB committee member is the investigator, sub-investigator, co-investigator of the study, or participates in such study.

4.7.2委員與該臨床研究計畫主要主持人有配偶、四親等內之血親或三親等內之姻親或曾有此關係。

The IRB committee member is the spouse, fourth-degree blood relative, or third-degree affines of the study investigator, or were previously of such relationship.

4.7.3委員與該臨床研究計畫有其他經委員會決議應迴避之非財務利益衝突。

The IRB committee members have other non-financial conflicts of interests with the study protocol that have been decided by the IRB.

5.作業流程 Process of operation

5.1流程

Process

程序 Procedure	權責 Rights and responsibilities	相關文件 Related documents
文件準備 Document preparation	行政人員 Administrative staff	保密及利益衝突協議書 Agreement on confidentiality and conflicts of interests
簽署 Signature	參與本委員會之相關人員 Relevant staff that attend IRB	
核章 Seal of approval	主任委員 Committee director	
關防用印 Seal of institution	行政室 Administrative office	
發放 Distribution	行政人員 Administrative staff	
保存 Record keeping	行政人員 Administrative staff	

5.2職責

Responsibilities

5.2.1 主任委員：所有保密及利益衝突協議書皆由行政主任委員核章。

Committee director: all agreement on confidentiality and COI must be signed by the committee director.

5.2.2 委員、諮詢專家、執行秘書、訪查或評鑑委員、參訪來賓皆須簽署保密及利益衝突協議書。

Committee members, consultants, executive secretary, visiting or accreditation members and visiting guests must sign the confidentiality and COI agreements.

5.2.3 行政人員(含工讀生)：須簽署保密及利益衝突協議書，並準備相關文件、協助簽署、用印，發放用印完成之文件及保存。

Administrative staff (including part-time students): must sign the confidentiality and COI agreements, and assist in the document preparation, signing, sealing, distribution of sealed document, and archiving.

5.3保密及利益衝突協議管理流程

Procedure for management of confidentiality and COI agreement

5.3.1 文件準備：行政人員將保密協議書遞交簽署人員。

Document preparation: administrative staff gives the confidentiality agreement to the signee.

5.3.1.1 新聘任的委員、諮詢專家、執行秘書、行政人員(含工讀生)於聘任時，其他相關人員於參與、查訪本會相關業務時，須簽署一份保密及利益衝突協議書。

Newly appointed committee members, consultants, executive secretary, and administrative staff (including part-time students) shall sign the confidentiality and COI agreement upon employment; other personnel during visiting and inspection of IRB affairs shall sign the same agreement.

5.3.1.2 保密/利益衝突協議簽署表格包括：

The confidentiality/COI signing forms include:

A「委員-保密/利益衝突協議」

Committee member-confidentiality/COI agreement

B「諮詢專家-保密/利益衝突協議」

Consultant-confidentiality/COI agreement

C「嚴重不良事件審查委員-保密/利益衝突協議」

Reviewer of SAE-confidentiality/COI agreement

D「行政人員-保密/利益衝突協議」

Administrative staff-confidentiality/COI agreement

E「參訪人員-保密/利益衝突協議」

Visitor-confidentiality/COI agreement

F「CONFIDENTIALITY AGREEMENT」

G「臨床試驗管理委員會-保密/利益衝突協議」

Clinical Trial Management Committee-confidentiality/COI agreement

H「臨床試驗管理委員會行政人員-保密/利益衝突協議」

Administrative staff of CTMC-confidentiality/COI agreement

I 「受試者代表/特殊族群及易受傷害族群代表-保密/利益衝突協議」

Subject representative/representative of special and vulnerable populations-confidentiality/COI agreement

J 「儲備委員-保密/利益衝突協議」

Reserve committee members-confidentiality/COI agreement

5.3.2 簽署者拿到保密/利益衝突協議書後，須仔細閱讀協議書內容。如有必要，簽署者可要求人委會行政人員解釋或說明文件的內容。

Upon receiving the agreement form, the signee must carefully read through the content. If necessary, the signee may request the administrative staff of the IRB to explain or describe the contents of the document.

5.3.3 簽署者如對協議書內容無異議，須在協議書內填上姓名、聯絡電話、住址及日期後，交還人委會行政人員。

If the signee has no objection to the content of the agreement, he/she will then fill in the names, contact telephone, address and dates, and return to the administrative staff of the IRB.

5.3.4 主任委員用印，呈院方蓋關防後，將協議書掃描成電子檔。

The agreement will be sealed by the committee director and officially sealed by the hospital management. The staff will then scan the agreement into electronic form.

5.3.5 人委會保存簽名的保密/利益衝突協議書正本，作為人委會紀錄，並將檔案儲存於人委會資料庫。將電子檔寄給簽署者。

The IRB keeps the original copy of the signed agreement form as official record, and archive the file in the IRB database. The electronic copy is then sent to the signee.

5.3.6 保密/利益衝突協議書效期：委員、諮詢專家、執行秘書、行政人員(含工讀生)經續聘任且保密/利益衝突協議書未修正者，可延續簽署之時效。若遇保密/利益衝突協議書內容修改時，其相關人員應重新簽署。

Valid period of the confidentiality/COI agreement: for committee members, consultants, executive secretary, administrative staff (and part-time students) that have been re-appointed and have not amended the content of the agreement, the validity of the signed agreement can be extended; re-signing of the agreement is required if the content has been altered.

5.4本委員會主任委員、副主任委員、委員/專家、執行秘書、行政人員、工讀生、評鑑/訪查人員及參訪人員均應遵守「利益迴避及保密原則」，對於被

提供之機密資訊和文件(以下簡稱〝保密資料〞)，同意採取正當的方法來保護保密資料，並遵守適當的法規(包括資料查詢法)。

The committee director, deputy director, committee members, consultants, executive secretary, administrative staff, part-time students, accreditation/inspecting personnel and visitors should comply with the "Principles of Confidentiality and Conflicts of Interests", and agree to taking correct measures to protect confident data ("confident information and document") and complying with appropriate legislatures (including Inquiries Act)

5.5隱私保護原則：

Principles of privacy protection:

5.5.1審查委員依據「新案初審審查意見表」進行審查，其中包含受試者資料機密性及隱私保護。

Reviewer conducts review according to the "Initial Review Comments Form" for new case, which includes subject data confidentiality and privacy protection.

5.5.2不能暴露受試者不欲讓別人知道的個人相關資料。

Cannot disclose any personal information the subject wishes to keep confidential.

5.5.3受試者同意書應詳細告知如何保護受試者個人隱私。

The informed consent form must describe in detail how the personal privacy of the subject is protected.

5.6保密原則

Principles of confidentiality

5.6.1 相關人員之保密原則如下：

Principles of confidentiality are as follow:

5.6.1.1 不能對任何第三人洩露因執行業務而知悉之保密文件內容。

Cannot disclose any confidential document encountered during institutional affairs to any

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third parties.

5.6.1.2 除經人委會授權，不能因任何其他目的使用保密資料。

Cannot use confidential data for other purposes without the authorization from the IRB.

5.6.1.3 不能以任何方法導致自己或第三者獲利。

Cannot use the information to obtain profits for self or third parties in any methods.

5.6.2 人委會之審查委員、諮詢專家、執行秘書、行政人員，於離職後均不得洩露人委會業務相關訊息。

Committee members, consultants, executive secretary and administrative staff that have resigned cannot disclose any information about the affairs of the IRB.

5.7利益衝突迴避原則：

Principles of conflicts of interests:

5.7.1 委員於審查時應謹守利益衝突迴避原則，如有以下情形應迴避審查：

Committee member shall strictly adhere to the principles of COI, and should be excused from the review if any of the following is applicable:

5.7.1.1 為人體試驗計畫之主持人、協同主持人、共同主持人或委託人。

The IRB committee member is the investigator, sub-investigator, co-investigator or sponsor of the study.

5.7.1.2 與主持人有配偶、四親等內之血親或三親等內之姻親或曾有此關係。

The committee member is the spouse, fourth-degree blood relative, or third-degree affines of the study investigator, or were previously of such relationship.

5.7.1.3 與人體試驗計畫委託人有聘僱關係。

Employment relationship with the study sponsor.

5.7.1.4 有具體事實，足認有偏頗之虞。

Sufficient evidence to indicate concerns of biases.

5.7.1.5 其他經審查會認有利益迴避之必要者。

Other conflicts of interests that have been decided by the IRB.

5.7.2 委員於審查會議時如有上述情形時，亦不得參與討論、表決：

Committee members may not participate in discussion and voting during the IRB meetings if any of the above situations applied:

5.7.3 委員與該試驗計畫委託人有下列關係時，應揭露之：

Committee members should disclose any of the following relationship with the study sponsor:

5.7.3.1 支薪之顧問

Paid consultant

5.7.3.2 本人、配偶與三親等以內之親屬對該試驗計畫委託人或團體之投資。

Investment made to the study sponsor or organization by the member, spouse or third-degree relative.

5.7.3.3 其他財務往來狀況足以影響案件之審查者。

Other financial interaction that may potentially influence the results of the study review.

5.7.4 委員與該試驗計畫委託人有下列財務之利益衝突時，應揭露之：

Committee members should disclose any of the following financial conflicts of interests with the study sponsor:

5.7.4.1 本人或其配偶、未成年子女於過去十二個月期間，自該臨床研究委託者所收受之報酬(如顧問費、演講費、出席費等)、捐贈、禮品及其他具金錢價值之給付，合計達十五萬元以上者。

The total value of remunerations (e.g. consultant fees, gratuities and attendance feeds), donations, gifts and payment of monetary values received by the committee members, their spouses and minor children in the past 12 months have amounted to NT$150,000 or more

5.7.4.2 本人或其配偶、未成年子女於過去十二個月期間，對該臨床研究計畫委託者之資產持股利 益(如股份、股票選
權等)達資本額 5%以上者。

The total value of the clinical trial generated share holder profits (e.g. shares, options) received by the committee members, their spouses and minor children in the past 12 months have amounted to 5% or more of the capital value.

5.7.4.3 本人或其配偶、未成年子女為該臨床研究所使用之專利或著作之所有權人或對該臨床研究 所使用之專利或著作獲有授權金。

The committee member, their spouses or minor children are the owner of the patents or publications used by the clinical study, or receive loyalties from the patents or publications used by the clinical study.

5.7.4.4 本人或其配偶、未成年子女自該臨床研究計畫委託者所收受之報酬數值可能受該計畫成果之影響。

The value of remuneration received by the committee member, their spouses or minor children from the study sponsor may be affected by the results of the study.

5.7.4.5 本人或其配偶、未成年子女為臨床研究計畫委託者之員工或董事。

The committee member, their spouses and minor children are employees, paid consultants or board members of the study sponsor.

5.8公告委員迴避審查事宜

Announcement of conflicts of interests

5.8.1 人委會委員同時為計畫主持人、共同或協同主持人，經確實迴避該計畫之審查及審查會議，於會後公告迴避審查事宜。

After being excused from the protocol review and review meetings, the IRB committee members shall disclose the conflicts of interests after the review meeting if he or she is the principal investigator, co- or sub-investigator of the protocol under review.

5.9當委員或諮詢專家被指派審查各類案件時，如有相關之利益衝突應主動揭露。

Committee members or consultants should directly disclose any conflicts of interests when appointed to review protocols.

6.附件 Attachment

6.1附件一(KMUH/IRB/AF/1.4-01/11.0) 委員-保密協議書

Attachment 1 (KMUH/IRB/AF/1.4-01/11.0) Committee Member - Confidentiality Agreement

6.2附件二(KMUH/IRB/AF/1.4-02/11.0) 諮詢專家-保密協議書

Attachment 2 (KMUH/IRB/AF/1.4-02/11.0) Consultant - Confidentiality Agreement

6.3附件三(KMUH/IRB/AF/1.4-03/11.0) 嚴重不良事件審查委員-保密協議書

Attachment 3 (KMUH/IRB/AF/1.4-03/11.0) Reviewer of SAE - Confidentiality Agreement

6.4附件四(KMUH/IRB/AF/1.4-04/11.0) 行政人員-保密協議書

Attachment 4 (KMUH/IRB/AF/1.4-04/11.0) Administrative Staff-Confidentiality Agreement

6.5附件五(KMUH/IRB/AF/1.4-05/11.0) 參訪人員-保密協議書

Attachment 5 (KMUH/IRB/AF/1.4-05/11.0) Visitors - Confidentiality Agreement

6.6附件六(KMUH/IRB/AF/1.4-06/11.0) CONFIDENTIALITY AGREEMENT

Attachment 6 (KMUH/IRB/AF/1.4-06/11.0) CONFIDENTIALITY AGREEMENT

6.7附件七(KMUH/IRB/AF/1.4-07/11.0) 臨床試驗管理委員會-保密協議書

Attachment 7 (KMUH/IRB/AF/1.4-07/11.0) Clinical Trial Management Committee - Confidentiality Agreement

6.8附件八(KMUH/IRB/AF/1.4-08/11.0) 臨床試驗管理委員會行政人員-保密協議書

Attachment 8 (KMUH/IRB/AF/1.4-08/11.0) Administrative Staff of CTMC - Confidentiality Agreement

6.9附件九(KMUH/IRB/AF/1.4-09/11.0) 受試者代表/特殊族群及易受傷害族群代表-保密協議書

Attachment 9 (KMUH/IRB/AF/1.4-09/11.0) Subject Representative/Representative of Special and Vulnerable Populations - Confidentiality Agreement

6.10附件十(KMUH/IRB/AF/1.4-10/11.0) 儲備委員-保密協議書

Attachment 10 (KMUH/IRB/AF/1.4-10/11.0) Reserve Committee Members - Confidentiality Agreement

6.11附件十一(KMUH/IRB/AF/1.4-11/11.0) 委員-利益衝突協議書

Attachment 11 (KMUH/IRB/AF/1.4-11/11.0) Committee Member – Conflicts of Interests Agreement

6.12附件十二(KMUH/IRB/AF/1.4-12/11.0) 受試者(團體)代表-利益衝突協議書

Attachment 12 (KMUH/IRB/AF/1.4-12/11.0) Subject (Group) Representatives - Conflicts of Interests Agreement

6.13附件十三(KMUH/IRB/AF/1.4-13/11.0) 諮詢專家-利益衝突協議書

Attachment 13 (KMUH/IRB/AF/1.4-13/11.0) Consultant - Conflicts of Interests Agreement