



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	4.2	檔案名稱 File name	研究團隊之利益衝突審議及處置 Management Conflict of Interest for Research Team		
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

規範臨床研究團隊利益衝突的申報方式、認定標準及處置辦法，以確保研究執行之客觀公正及落實受試者保護。

To regulate the declaration approach, the determining criteria and handling procedures of the research team conflict of interest, in order to ensure the objectiveness and impartiality of study implementation and achieve the protection of subject's rights.

2. 適用範圍 Scope

適用所有人體研究案。

It is applicable to all human studies.

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 (2014年10月)

Guidelines of Good Clinical Practice (October 2014)

3.4 AAHRPP Domain I. Element 1.6A. (2016/10)

3.5 AAHRPP Domain I. Element 1.6B. (2016/10)

3.6 AAHRPP Domain II. Element 1.D. (2016/10)

3.7 AAHRPP Domain III. Element 1.B. (2016/10)

4. 名詞定義 Terminology

4.1 利益衝突 (Conflict of Interest; COI)：指個人利益/次要利益導引專業判斷或



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行動，會對受試者權益/主要利益造成不當影響而產生風險。例如計畫主持人/研究人員/審查委員有個人利益/次要利益，可能影響其研究執行或研究審查的客觀公正性，導致產生對受試者權益/主要利益或安全不當之影響。

Conflict of Interest (COI): refers to personal interests/secondary interests that lead to professional judgement or actions, and may cause inappropriate effects on the rights/primary interests of the subjects and thus generate risks. For example, the PI/research personnel/reviewers have personal interests/secondary interests that may affect the implementation of the study or the objectiveness and impartiality of study review, and thus lead to causing inappropriate impacts on the rights/primary interests or the safety of the subjects.

4.2 財務利益衝突(Financial Conflict of Interest)：財務利益直接且有意義地影響研究之設計、執行、報告，或對機構應盡的義務和責任。上述財務利益包括但不限於：

Financial Conflict of Interest: the financial conflict of interest directly and significantly affects the design and implementation of the study, or the obligation and responsibility for the institutes. The above financial conflict of interest includes but is not limited to the person who:

4.2.1 與試驗委託者/廠商有聘僱關係

Has employment relationship between the sponsor/manufacturer

4.2.2 為試驗委託者/廠商之主管或負責人

Is the chief or person-in-charge of the sponsor/manufacturer

4.2.3 為試驗委託者/廠商長期支薪之顧問

Is the long-term paid consultant of the sponsor/manufacturer



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4.2.4 試驗委託者提供年薪、產品或服務

Whose annual salary, products or services are provided by the sponsor

4.2.5 擁有計畫贊助公司或其產品之私有股息(如公司股票)

Has private stock dividend (e.g. company stocks) from the sponsor or its products

4.2.6 獲得的股息(包括股票或其相等值)或計畫案的經費贊助金額

Obtain stock dividend (including stocks or property with equivalent value) or funding source for the study

4.2.7 獲得與研究有關的藥品/產品/技術之所有權(包括專利、商標、商業機密、版權)

Obtain the ownership (including the patents, trademarks, commercial confidentiality and copyrights) of study-related medicinal products/products/technology

4.2.8 收取或預期收到補助款足以影響研究的結果

Receive or expected to receive reimbursement that is sufficient to affect study results

4.3 顯著財務利益：指下列情形之一

Significant financial interests: refer to one the following conditions:

4.3.1 試驗委託者所提供之年薪、產品及服務共超過新台幣 15 萬元

The annual salary, products and services provided by the sponsor is totally over NT\$150,000.

4.3.2 獲得的股息(包括股票或其相等值)共超過新台幣 15 萬元，或 5%計畫案的經費贊助金額。



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The obtained stock dividend (including stocks or property with equivalent value) is totally over NT\$150,000, or beyond 5% of the study protocol's funding source.

4.4 非財務關係之利益衝突：指下列情形之一

Non-financial conflict of interest: refers to one the following conditions

4.4.1 研究人員或其配偶擔任本計畫之臨床研究委託者及其相關實體之不支酬主管職或顧問。

The research personnel or their spouses are the not-paid chief or consultant of the sponsor or relevant entity of the clinical study.

4.4.2 本研究以研究人員的直屬部屬、助理或學生做為研究的對象

This study uses research personnel's immediate subordinates, assistants or students as study subjects.

5.作業內容 Scope of operation

5.1 流程 Process

程序 Procedure	負責人/單位 Person-in-charge/Unit	相關文件 Related documents
利益揭露 Interest disclosure	計畫主持人、研究人員 Principal Investigator, research personnel	財務利益衝突申報表 The declaration form of financial conflict of interest
利益衝突之評估 The assessment of conflict of interest	審查委員 Reviewers	財務利益衝突申報表 The declaration form of financial conflict of interest
利益衝突之處理 The handling of conflict of interest	審查委員 Reviewers	顯著財務利益評估暨處置計畫 說明表 Significant financial interest assessment and handling plan description form



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歸檔 Archiving	行政人員 Administrative staff	財務利益衝突申報表、顯著財務利益評估暨處置計畫說明表 The declaration form of financial conflict of interest, significant financial interest assessment and handling plan description form
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5.2 職責 Responsibilities

5.2.1 計畫主持人/研究人員：申報自身、配偶及未成年子女與計畫相關之利益衝突。

Principal Investigator/research personnel: shall declare study-related personal/next of kin's conflict of interest.

5.2.2 審查委員：需評估並決定研究團隊之利益衝突及處理。

Reviewers: required to evaluate and decide the conflict of interest and handling for the research team.

5.3 細則 Rules

5.3.1 利益衝突申報(Disclosure)

Disclosure of conflict of interest

5.3.1.1 計畫主持人/研究人員於計畫初次送審時，需申報自身、配偶及未成年子女與計畫相關之利益，填寫研究人員財務利益衝突申報表(附件一)。

The PI/research personnel are required to declare personal/next of kin's study-related interests and fill in Research Personnel Financial Conflict of Interest Declaration Form (Attachment 1) during the submission of initial review.



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5.3.1.2 申報內容有顯著財務利益改變時，須於 30 日內更新申報資料。

If the contents of the declaration have significant changes in financial interests, they shall be renewed within 30 days.

5.3.1.3 申報內容有顯著財務利益時，計畫主持人需另填寫顯著財務利益評估暨處置計畫說明表(附件二)。

If the contents of the declaration have significant financial interests, the PI is required to fill in an additional Significant Financial Interest Assessment and Handling Plan Description Form (Attachment 2).

5.3.2 利益衝突之評估

Assessment of conflict of interest

5.3.2.1 委員審查案件時，應依據以下考量，評估研究團隊與試驗委託者或廠商之間是否有利益衝突，並提供相關處置建議：

When reviewing cases, the reviewers shall evaluate whether there are conflicts of interests between the research team and the sponsor or the manufacturer based on the following considerations, and thus provide corresponding handling recommendations:

A.研究的科學學術價值。

The scientific/academic value of the study.

B.研究對受試者可能產生的風險性有多大。

What is the risk level toward the subjects caused by the study.

C.所持有之財務利益的種類以及金額。

The types and financial amount of the possessed financial interest.



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D.財務利益是否對受試者產生不良影響。

Does the financial interest have adverse impacts on the subjects.

E.財務利益是否會影響該研究的執行與其結果。

Does the financial interest will affect the implementation and the results of the study.

F.涉及利益衝突的人員，是否具有獨特的能力、經驗..等背景，是執行該臨床研究之唯一人選。

Do personnel that have conflict of interest have unique backgrounds such as abilities, experience, etc. and thus make them the only candidate investigators of the clinical study.

5.3.3 顯著利益衝突之處理

The handling of significant conflict of interest

5.3.3.1 委員會審查案件時，須提供減低或迴避利益衝突之處置建議：

When the committee is reviewing the case, handling recommendations to reduce or avoid conflict of interest must be provided:

於受試者同意書公開所持有之顯著財務利益。

Publish all possessed significant financial interest in the subject ICF.

A.設置獨立之資料安全監督機制。

Establish an independent DSMB mechanism.

B.涉及利益衝突的人員迴避部分的研究，例如計畫主持人避免執行取得受試者同意或是資料分析等工作。

Personnel involving conflict of interest shall avoid part of the



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studies. For example, the PI shall avoid obtaining subject's consents or data analysis, etc.

C. 撤除所有的顯著財務利益。

Revoke all significant financial interests.

D. 避免執行有顯著財務利益衝突之計畫案。

Avoid implementing study protocols with significant financial conflict of interest.

5.3.3.2 處理原則

Handling principles

A. 研究對受試者可能產生的風險不大(藥品第二類風險或醫療器材低風險)時，處理方式得為 5.3.3.1 A、B、C。

When the study may not generate great risks toward the subjects (for medicinal products, Class II risk, or for medical devices, low risk), the handling could be following Section 5.3.3.1 A, B, C.

B. 研究對受試者可能產生的風險大(藥品第三類風險或醫療器材中、高風險)時，處理方式得為 5.3.3.1 A、B、C、D、E。

When the study may generate great risks toward the subjects (for medicinal products, Class III risk, or for medical devices, medium-to-high risk), the handling could be following Section 5.3.3.1 A, B, C, D, E.

C. 涉及利益衝突的人員，具有獨特的能力、經驗..等背景，為執行該臨床研究之唯一人選時，處理方式得為 5.3.3.1 A、B、C、D。

If the personnel involving conflict of interest have unique



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backgrounds such as abilities, experience, etc. and thus make them the only candidate investigators of the clinical study, the handling could be following Section 5.3.3.1 A, B, C, D.

D. 審查會依對受試者可能產生的風險，得決定是否核准研究計畫。

The review meeting will decide whether the study protocol will be approved based on the potential risks toward the subjects.

5.3.4 監測及利益衝突違規之處置機制

The handling mechanism for monitoring the violation of conflict of interest

5.3.4.1 人委會審查涉及利益衝突的計畫年度報告時，須確認確實遵循利益衝突處置建議，迴避或減免利益衝突。

When the IRB review is involving the conflict of interest of the annual report, it is required to comply with the handling recommendations to avoid or reduce conflict of interest.

5.3.4.2 如發現不實利益衝突事件，採實地訪視，不定期稽核研究團隊是否遵循利益衝突處置建議，並將結果呈報受試者保護中心。

If any conflicts of interests are found, site visits will be scheduled to audit whether the core team has complied with the handling recommendations and reported the results to the CHSP from time to time.

5.3.4.3 違反本院利益衝突處置規範者，將提會討論並依 SOP 4.2「研究團隊之利益衝突審議及處置」進行相關懲處，並知會受試者保護中心。

For those who violate the KMUH handling regulations for conflict of



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interest, they will be reported to the board meeting for discussion in accordance with SOP 4.2 “Management Conflict of Interest for Research Team” for relevant sanctions. The results will also be reported to the CHSP.

5.3.5 歸檔

Archiving

5.3.5.1 研究人員利益衝突申報表及審查決議的文件應歸檔管理。

The research personnel’s conflict of interest declaration form and review resolution files shall be archived.

5.3.5.2 財務利益衝突揭露與處理紀錄，結案存查後相關紀錄至少保存三年。

The financial conflict of interest disclosure and handling record shall be retained for at least 3 years after case closed.



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6.附件 Attachment

6.1 附件一 (KMUH/IRB/AF/4.2-01/11.0) 研究人員財務利益衝突申報表

Attachment 1 (KMUH/IRB/AF/4.2-01/11.0) Research Personnel Financial
Conflict of Interest Declaration Form

6.2 附件二 (KMUH/IRB/AF/4.2-02/11.0) 顯著財務利益係評估暨處置計畫說明表

Attachment 2 (KMUH/IRB/AF/4.2-02/11.0) Significant Financial Interest
Assessment and Handling Plan Description Form

6.3 附件三 (KMUH/IRB/AF/4.2-03/11.0) 臨床研究人員-顯著利益宣告揭露聲明書