臺 中 榮 民 總 醫 院
Taichung Veterans General Hospital

管 制 文 件 訂 修 廢 紀 錄 表
Record of Composition and Revisions of Controlled Documents

文件編號 Document Number	IRB-本會-工作常規-2026 IRB-Regulations of Operation-2026	文件名稱 Title	臨床研究利益衝突審議及處置管理程序書 SOP for Handling Conflict of Interest in Clinical Study
訂定單位 Composed by	人體研究倫理審查委員會 The IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □confidential □highly confidential
適用單位 Applied to	□全院 □**All units in the hospital** ■其他，請註明：人體研究倫理審查委員會 ■**Other (Please specify): The IRB Committees**		

版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
A	17	新訂。 Newly composed.	20190527
B	18	1. 依據 AAHRPP 國際認證委員之建議進行增修。 1. The following modifications were made according to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) reviewers. 2. 新增 5.2.1.3：若有財務利益狀況/非財務關係之改變時（自新取得財務利益之日起回溯 12 個月之財務利益總和達顯著利益門檻、或新增研究人員等）應於 30 日內更新申報資料。 2. Added Item 5.2.1.3: In the event of a change in the financial interest/non-financial relationship (the sum of the financial benefits over the last 12 months reaches the significant interest threshold calculating from the first day of acquiring new financial benefits or the addition of researchers etc), the related report of the proposal should be updated and sent to the IRB within 30 days. 3. 新增 5.4.4：人體研究倫理審查委員會參考利益衝突審議小組之決議，決定是否通過試驗/研究計畫/核准試驗/研究計畫繼續執行，並確認是否符合試驗/研究委託機構以及主管機關的通報規定。 3. Added Item 5.4.4: Based on the resolution made by the conflict of interest review taskforce, the IRB decides whether to pass the trial/study protocol or approve trial/study protocol to be continued, and verify whether it complies with the reporting requirements defined by the sponsor and competent authority.	

臺中榮民總醫院
Taichung Veterans General Hospital

管制文件訂修廢紀錄表
Record of Composition and Revisions of Controlled Documents

文件編號 Document Number	IRB-本會-工作常規-2026 IRB-Regulations of Operation-2026	文件名稱 Title	臨床研究利益衝突審議及處置管理程序書 SOP for Handling Conflict of Interest in Clinical Study
訂定單位 Composed by	人體研究倫理審查委員會 The IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □confidential □highly confidential
適用單位 Applied to	□全院 □**All units in the hospital** ■其他，請註明：人體研究倫理審查委員會 ■**Other (Please specify): The IRB Committees**		

版次 Version	頁數 No. Pages	文件修訂摘要 Summary of Revisions of the Document	實施日期 Date of Implementation
B	18	4. 修改 5.5.5.2 為研究人員未配合財務利益衝突的政策和程序。 4. Revised 5.5.5.2: Research personnel shall be educated about conflict of interest policy or procedure when they do not comply with related policies and procedures. 5. 修改 5.5.5 標題為「需立即進行教育訓練(educational training)的情況」 5. Revised the title of Item 5.5.5: Educational training is required immediately when:	20191018
C	18	1. 修改參考文件 3.2 為「藥品優良臨床試驗作業準則」109 年 08 月 28 日衛生福利部部授食字第 1091407788 號令修正。 1. Updated reference 3.2 into ““Regulations for Good Clinical Practice” amended on August 28 2020, pursuant to Ministry of Health and Welfare Bu-Shou-Shi-Zi No. 1091407788.” 2. 文字校正。 2. Fixed typos. 3. 原 5.3.3 內容修改為 5.4.2。 3. Item 5.3.3 was moved to item 5.4.2. 4. 修改原 5.4.2 標號為 5.4.3。 4. Changed the original item number 5.4.2 to 5.4.3. 5. 刪除原 5.4.3 內容。 5.Deleted item 5.4.3.	20210528

臺中榮民總醫院
Taichung Veterans General Hospital

管制文件訂修廢紀錄表
Record of Composition and Revisions of Controlled Documents

文件編號 Document Number	IRB-本會-工作常規-2026 IRB-Regulations of Operation-2026	文件名稱 Title	臨床研究利益衝突審議及處置管理程序書 **SOP for Handling Conflict of Interest in Clinical Study**
訂定單位 Composed by	人體研究倫理審查委員會 The IRB Committees	機密等級 Level of Confidentiality	■普通 □密件 □極機密 ■Unclassified □confidential □highly confidential
適用單位 Applied to	□全院 □**All units in the hospital** ■其他，請註明：人體研究倫理審查委員會 ■**Other (Please specify): The IRB Committees**		

版次 Version	頁數 No. Pages	文件修訂摘要 **Summary of Revisions of the Document**	實施日期 Date of Implementation
D	18	1. 更改文件名稱。 1. The title of the document was revised. 2. 原「第一/二人體研究倫理審查委員會」修改為「人體研究倫理審查委員會」。 2. The original “The First/Second IRB Committees” was renamed “The IRB Committees”. 3. 依據 AAHRPP 國際認證委員之建議進行增修。 3. The following modifications were made according to the recommendations of AAHRPP (Association for the Accreditation of Human Research Protection Program) reviewers. 4. 修改 5.4.4 文句 4. The wording in item 5.4.4 was modified. 5. 新增 5.6：利益衝突審議小組將定期評估受試者保護中心提供之年度「機構利益衝突」相關資料，若有涉及利益衝突之情況，將提報人體研究倫理審查委員會。 5. Added item 5.6: The Conflict of Interest Review Task Force will regularly evaluate the annual "Institutional Conflict of Interest" information provided by the Human Research Protection Center, and if there is a conflict of interest, it will be reported to IRB. 6. 修改原 5.6 標號為 5.7。 6. Changed the original item number 5.6 to 5.7.	20230717

臺中榮民總醫院
2023.08.10
參考文件

訂修廢 Composed/Revised/Deleted	審核 **Reviewed**	核准 **Approved**

本文件已經權責主管正式核准，
核章紀錄文件本儲放於 SOP 管理中心

※管制文件不得擅自塗改及做記號並禁止影印。
※本文件以 KM 系統為最新版本，紙本發行需經 SOP 管理中心核章，嚴禁自行列印。
※Changing, marking, or copying controlled documents without permission is prohibited.
※The latest version of this document in the Knowledge Management System (KMS) takes precedence. Distribution of hard copies of this document must be approved and stamped by the SOP Administrative Center. Copying without permission is strictly prohibited.

臺中榮民總醫院
Taichung Veterans General Hospital

管制文件訂修廢會審單
Review Form of Composition and Revisions of Controlled Documents

文件編號 Document Number	IRB-本會-工作常規-2026 IRB-Regulations of Operation-2026	文件名稱 Title	臨床研究利益衝突審議及處置管理程序書 SOP for Handling Conflict of Interest in Clinical Study

會辦單位 Processing Unit	審查意見 Review Comments	會辦單位主管 Head of Processing Unit
	無跨部科會審需求。 There is no need for review by other departments or divisions.	

臺中榮民總醫院
2023.08.10
參考文件

※請各會辦單位主管惠賜審查意見後核章，必要時得直接與訂定單位協商。

※The head of each processing unit is advised to provide comments before signing/stamping to approve. If needed, it is recommended that the head of each processing unit discuss with the unit that made the SOP.

1.目的

臺中榮民總醫院(以下簡稱本院)為規範臨床試驗/研究相關之財務利益衝突審議程序、認定標準及處置辦法，以確保研究的客觀公正與落實受試(訪、檢)者的保護機制，特制訂本管理程序書。

1. Purpose

The purpose of this SOP is to provide guidance for reviewing, identifying, and handling conflict of interest in clinical studies at Taichung Veterans General Hospital, so as to ensure objective and fair research and to implement subject protection mechanism.

2.適用範圍

此管理程序書適用於所有臨床試驗/研究之審查，無論臨床試驗/研究經費的來源皆採一致標準，以避免因利益衝突，而影響對受試(訪、檢)者權益之保護。

2. Scope

This SOP applies to the review of all clinical studies; same review standards shall be adopted for all studies regardless of the source of funding to ensure that the protection of the subjects' rights and welfare is not affected by conflict of interest.

3.參考文件

3. References

3.1「人體研究法」總統華總一義字第 10000291401 號令制定公布全文 26 條，民國 100 年 12 月 28 日施行。

3.1 Human Subjects Research Act, promulgated as per the Presidential Order Hua-Zong-Yi-Yi-Zi No. 10000291401 dated 28 December 2011.

3.2「藥品優良臨床試驗作業準則」109 年 08 月 28 日衛生福利部部授食字第 1091407788 號令修正。

3.2 "Regulations for Good Clinical Practice" amended on August 28 2020, pursuant to Ministry of Health and Welfare Bu-Shou-Shi-Zi No. 1091407788.

3.3「人體試驗管理辦法」105 年 4 月 14 日衛生福利部衛部醫字第 1051662154 號令修正。

3.3 Regulations on Human Trials, promulgated by the Ministry of Health and Welfare, amended on 14 April 2015, pursuant to Wei-Bu-Yi-Zi No. 1051662154.

3.4 AAHRPP Element I.6.B. The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of Researchers and Research Staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The Organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate.

4.名詞定義

4. Definitions

4.1 財務利益(Financial Interest)

指具貨幣價值之任何項目，包括但不限於，勞務款項（例如，顧問費、演講費、鐘點費、出席費、服務收入或類似費用、與臨床試驗/研究相關且可能受試驗/研究結果所影響的金錢補助等）、股權（例如，股票、認股權或其他與試驗/研究相關且可能受研究結果所影響的所有權利益），以及智慧財產權（例如，專利、著作權和該等權利之權利金），下列各款不屬於前條所稱財務利益：

4.1 Financial Interest

Financial interest refers to any items of monetary value, including but not limited to, labor service payment (e.g. consulting fees, honoraria for speakers, hourly wages, attendance fees, service revenue or similar expenses, and stipends related to the study and potentially affected by the study result), equity (e.g. stock, stock options, or titles related to the study and potentially affected by the study result), and

intellectual property rights (e.g. patent, copyright, and royalty thereof), exclusive of the following:

4.1.1 由臨床試驗/研究委託者支付給本院，再經由本院發給個人，因執行臨床試驗/研究所需，且臨床試驗/研究合約所明訂之合理費用。

4.1.1 The amount of reasonable expenses needed for the implementation of the study paid by the sponsor to TCVGH and then by TCVGH to individuals involved in the study.

4.1.2 持有共同基金。

4.1.2 Mutual fund holdings

4.1.3 參加公立或非營利機構所舉辦之學術活動、委員會、專家小組或類似會議，且與該臨床試驗/研究計畫不相關，所獲得之演講費、鐘點費、出席費、服務收入或類似費用。

4.1.3 Honoraria for speakers, hourly wages, attendance fees, service revenue or similar expenses for participating in academic activities, committees, expert groups or other similar meetings organized by public or non-profit organizations and unrelated to the study.

4.2 個人之顯著財務利益（Individual Significant Financial Interest）：指下列任一：

4.2 Individual Significant Financial Interest, referring to any of the following circumstances:

4.2.1 研究人員與其配偶以及未成年子女自臨床研究計畫相關之單一臨床研究委託者及其相關的實體所收受之款項總額，於過去十二個月期間，超過新台幣 150,000 元(約 5000 美元)。

4.2.1 An investigator or research team member, his/her spouse and dependent children have received more than NT$150,000 (approximately US$5,000) in the past 12 months from the payment of a single sponsor of the study and related entities.

4.2.2 研究人員與其配偶以及未成年子女自臨床研究計畫相關之臨

床研究委託者及其相關的實體之股權總額，符合下列任一條件：參考公開價格、或其他公平市場價值之合理衡量認定下，價值超過新台幣 150,000 元(約 5000 美元)；或所代表任何單一實體之所有股權超過 5%。

4.2.2 An investigator or research team member, his/her spouse and dependent children have received more than NT$150,000 (approximately US$5,000) worth of equities or more than 5% of the total equities held by any entity they represent from a single sponsor of the study and related entities; the value of the equities shall be determined by referencing public market values or any other fair market values.

4.2.3 持有與臨床研究計畫相關之智慧財產權（例如，專利、著作權和該等權利之權利金）。

4.2.3 The ownership of intellectual property rights related to the study (e.g. Patents, copyrights, or any royalties of use thereof).

4.3 機構之顯著財務利益（Institutional Significant Financial Interest）：指下列任一

4.3 Institutional Significant Financial Interest, referring to any of the following circumstances:

4.3.1 試驗/研究委託者、試驗/研究使用之藥品或醫療器材之提供者等，對本院捐贈超過價值新臺幣 3,000,000 元(約 10 萬美元)。

4.3.1 The sponsor of the study or the provider of the investigational drug or medical device has made more than NT$3,000,000 (approximately US$100,000) worth of cash or in-kind donations to TCVGH.

4.3.2 本院為該臨床試驗/研究所使用之專利或著作之所有權人，或獲有智慧財產權授權金或技術移轉等利益。

4.3.2 TCVGH is the owner of the patent or work used in the study, or receives IPR license fees or other benefits from

transfer of technology.

4.3.3 本院醫療、醫事及研究部門之一級(含)以上主管，為該臨床試驗/研究計畫所使用之專利或著作之所有權人或獲有智慧財產權授權金。

4.3.3 The chair or director of a TCVGH first-level medical, administrative or research department is the owner of the patent or work used in the study, or receives IPR license fees.

4.3.4 本院醫療、醫事及研究部門之一級(含)以上主管與其配偶以及未成年子女自單一試驗/研究委託者及其相關的實體所收受之款項總額，於過去 12 個月期間，超過新臺幣 150,000 元。

4.3.4 The chair or director of a TCVGH first-level medical, administrative or research department, his/her spouse and dependent children have received payment of more than NT$150,000 from a single sponsor of the study and related entities in the past 12 months.

4.3.5 本院醫療、醫事及研究部門之一級(含)以上主管與其配偶以及未成年子女自單一試驗/研究委託者及其相關的實體之股權總額，符合下列任一條件：參考公開價格、或其他公平市場價值之合理衡量認定下，價值超過新臺幣 150,000 元；或所代表任何單一實體之所有股權超過 5%。

4.3.5 The chair or director of a TCVGH first-level medical, administrative or research department, his/her spouse and dependent children have received more than NT$150,000 worth of equities or more than 5% of the total equities held by any entity they represent from a single sponsor of the study and related entities; the value of the equities shall be determined by referencing public market values or any other fair market values.

4.4 利益衝突(Conflict of Interest; COI)：

指個人利益/次要利益導引專業判斷或行動，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。

4.4 Conflict of Interest (COI):

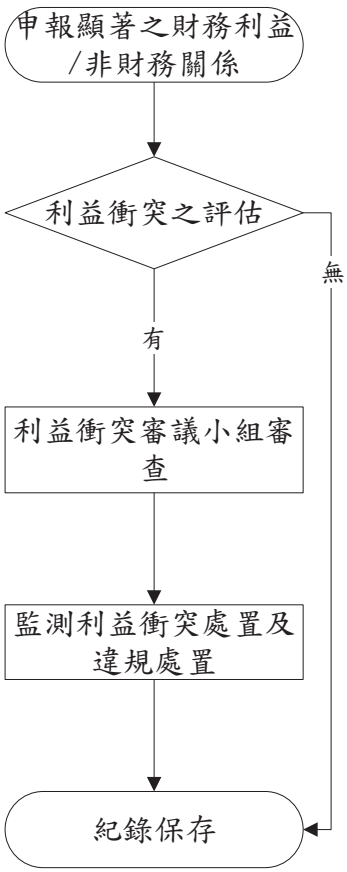
"Conflict of Interest; COI" refers to situations in which personal interests or secondary interests may compromise a researcher's professional judgment or behavior and may cause a negative impact or risk to the subjects' rights or primary interests. For example, a situation in which the principal investigator, research team member, or reviewer has personal or secondary interests may affect the objectivity or impartiality of the conduct or review of the research, which may lead to a negative impact on the subjects' rights, primary interests, or safety.

5.作業內容

5. Procedure

5.1 人體研究倫理審查委員會臨床研究利益衝突審議及處置流程圖

5.1 Flow Chart of the SOP for Handling Conflict of Interest in Clinical Study

流程 Flow Chart	權責 Responsible Personnel	相關文件 Relevant Documents
	計畫主持人/共(協)同主持人/研究人員 PI/Co-I/Sub-I/ Researcher	顯著財務利益暨非財務關係申報表 Statement of Disclosure of Significant Financial Interests and Non-financial Relationships
	承辦人員/審查委員/(副)主任委員 Staff/Reviewers/ (Vice) Chair	顯著財務利益暨非財務關係申報表 Statement of Disclosure of Significant Financial Interests and Non-financial Relationships
	利益衝突審議小組/審查委員 Conflict of Interest Review Task Force/Reviewers	相關送審文件/顯著財務利益暨非財務關係申報表 Relevant Submission Documents/ Statement of Disclosure of Significant Financial Interests and Non-financial Relationships
	利益衝突審議小組 Conflict of Interest Review Task Force	計畫執行期間之年度報告 Annual report during the execution of the Study
	承辦人員 Staff	相關送審文件/顯著財務利益暨非財務關係申報表 Relevant Submission Documents/ Statement of Disclosure of Significant Financial Interests and Non-financial Relationships

5.2 申報顯著之財務利益/非財務關係

5.2 Disclosure of Significant Financial Interests/Non-financial Relationships

5.2.1 計畫主持人於提出研究計畫送審時，每位研究人員(包含計畫主持人/共同主持人/協同主持人/研究人員)均應申報是否持有與臨床研究計畫相關之顯著財務利益以及可能構成利益衝突之非財務關係：

5.2.1 With the principal investigator's submission of a study protocol, each research team member (including the principal investigator, co-investigator, sub-investigator, and researchers) shall submit a statement of disclosure of significant financial interests and other non-financial relationships that may cause conflict of interests related to the study protocol.

5.2.1.1 填寫「顯著財務利益暨非財務關係申報表」以供人體研究倫理審查委員會(以下簡稱本會)審查。

5.2.1.1 Each research team member shall complete the "Statement of Disclosure of Significant Financial Interests and Non-financial Relationships" and submit it to the Institutional Review Board (IRB) for review.

5.2.1.2 若申報內容有顯著財務利益時，則需另行填寫「顯著財務利益/非財務關係評估暨處置計畫說明表」。

5.2.1.2 If any significant financial interest is stated in the "Statement of Disclosure of Significant Financial Interests and Non-financial Relationships," another form of the "Assessment and Plan of Handling Significant Financial Interests and Non-financial Relationships" shall be completed and submitted.

5.2.1.3 若有財務利益狀況/非財務關係之改變時(自新取得財務利益之日起回溯 12 個月之財務利益總和達顯著利益門檻、或新增研究人員等)應於 30 日內更新申報資料。

5.2.1.3 In the event of a change in the financial

interest/non-financial relationship (the sum of the financial benefits over the last 12 months reaches the significant interest threshold calculating from the first day of acquiring new financial benefits or the addition of researchers etc), the related report of the proposal should be updated and sent to the IRB within 30 days.

5.2.2 下列各款不屬於前條所稱財務利益：

5.2.2 The following circumstances do not constitute the financial interest referred to in the preceding paragraph:

5.2.2.1 由臨床試驗/研究委託者支付給本院，再經由本院發給個人，因執行試驗/研究所需，且試驗/研究合約所明訂之合理費用。

5.2.2.1 The amount of reasonable expenses needed for the implementation of the study paid by the sponsor to TCVGH and then by TCVGH to individuals involved in the study.

5.2.2.2 持有共同基金。

5.2.2.2 Mutual fund holdings

5.2.2.3 參加公立或非營利機構所舉辦之學術活動、委員會、專家小組或類似會議，且與該試驗/研究計畫不相關，所獲得之演講費、鐘點費、出席費、服務收入或類似費用。

5.2.2.3 Honoraria for speakers, hourly wages, attendance fees, service revenue or similar expenses for participating in academic activities, committees, expert groups or other similar meetings organized by public or non-profit organizations and unrelated to the study.

5.2.3 可能構成利益衝突之非財務關係，指下列任一：

5.2.3 The non-financial relationship, which might constitute a conflict of interest, shall refer to any of the following circumstances:

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

5.2.3.1 Any research team member or his/her spouse holds a non-paying position of supervisor or consultant for the sponsor and related entities.

5.2.3.2 本臨床試驗/研究以試驗/研究人員的直屬部屬、助理或學生做為試驗/研究對象

5.2.3.2 The subjects of the study are immediate subordinates, assistants or students of the research personnel.

5.2.4 計畫主持人(包含共同主持人、協同主持人)於提出臨床試驗/研究計畫書時，應申報是否本院對該試驗/研究計畫案持有下列各款之財務利益，供本會審查：

5.2.4 When the principal investigator submits the study protocol, the principal investigator (co-investigator or sub-investigator) shall declare if TCVGH holds any of the following financial interests to facilitate IRB review of the protocol:

5.2.4.1 本院為該臨床試驗/研究所使用之專利或著作之所有權人。

5.2.4.1 TCVGH is the owner of the patent or work used in the study.

5.2.4.2 本院對該臨床試驗/研究所使用之專利、著作或技術，獲有智慧財產權授權金或技術移轉等利益。

5.2.4.2 TCVGH receives IPR license fees or other benefits from transfer of technology for the patent, work or technology used in the study.

5.2.4.3 本院醫療、醫事、教學及研究部門之一級(含)以上主管，為該試驗/研究計畫所使用之專利或著作之所有權人或獲有智慧財產權授權金。

5.2.4.3 The chair or director of a TCVGH first-level medical, administrative or research department is the owner of the patent or work used in the study, or receives IPR license fees.

5.2.5 若申請之臨床試驗/研究計畫受美國衛生福利部(US Department of Health and Human Services)管轄，試驗/研究相關人員必須揭露過去 12 個月期間，是否曾經接受與其職責相關之贊助/補助交通費(sponsored travel)。

5.2.5 If the study is regulated by US Department of Health and Human Services, research personnel shall disclose if they had received any sponsored travel in the past 12 months related to their duties in the study.

5.2.5.1「交通費贊助/補助」指贊助商或機構代表試驗/研究人員支付費用，不直接交給試驗/研究人員。

5.2.5.1 “Sponsored travel” refers to the sponsor or the representative of the sponsoring organization paying for travel expenses rather than directly paying the research personnel.

5.2.5.2「職責相關」指代表本院所執行之臨床試驗/研究、專業諮詢、教學業務，或擔任本會、利益衝突審議小組等委員會之成員。

5.2.5.2 “Related to their duties in the study” refers to duties including representing the study conducted by TCVGH, professional consultation, teaching, serving as an IRB member, or serving as a member of the Conflict of Interest Review Task Force.

5.2.5.3 揭露內容包括：贊助之廠商或機構、目的、目的地及時間。

5.2.5.3 The following information shall be disclosed: The sponsoring company or organization, the purpose, the destination and the time of the travel.

5.2.5.4 不須揭露之贊助機構：政府機關、大學或研究所等高等教育機構及其隸屬研究單位、教學醫院及醫學中心。

5.2.5.4 The following sponsors do not need to be disclosed: Governmental organizations, higher education institutions such as universities or graduate institutes

and their affiliated research units, teaching hospitals and medical centers.

5.3 利益衝突之評估

5.3 Conflict of Interest Assessment

5.3.1 IRB 下設有利益衝突審議小組，就潛在之利益衝突案件進行審查，並提供減免、迴避利益衝突之處置建議。小組召集人為主任委員，小組成員 4-6 位以機構外委員為原則，由小組召集人邀請擔任。

5.3.1 A “Conflict of Interest Review Task Force” is set up under supervision of the IRB to review potential conflict of interest cases and to give suggestions regarding handling, reducing, and avoiding conflicts of interest. The IRB Chair serves as the Coordinator of the Conflict of Interest Review Task Force and invites 4 to 6 non-TCVGH-affiliated members to serve in the Task Force.

5.3.2 IRB 受理申報文件，確認每一臨床試驗/研究計畫是否有個人或機構的顯著財務利益。若有顯著財務利益或可能構成利益衝突之非財務關係之案件，將送請利益衝突審議小組審查。

5.3.2 Upon receipt of a statement of disclosure, the IRB shall verify if any personal or institutional significant financial interest is involved in the study. If any significant financial interest is involved in the study, or if any non-financial relationship may constitute conflict of interest, the case shall be submitted to the Conflict of Interest Review Task Force for review.

5.4 利益衝突審議小組審查

5.4 The Review and Suggestions by the Conflict of Interest Review Task Force

5.4.1 利益衝突審議小組委派一位小組審查委員進行審查，審查結束後將審查意見通知計畫主持人。

5.4.1 The Conflict of Interest Review Task Force shall assign a member from the Task Force to review each conflict of

interest case. After the review is completed, the principal investigator shall be informed of the review comments.

5.4.1.1 審查結果為「推薦」，則將審查意見提交予利益衝突審議小組，並將小組決議交付秘書處行政人員，排入最近一次 IRB 大會審查，以決定是否通過。

5.4.1.1 If the result is “Recommended, ”the reviewer’s opinions will be submitted to the Conflict of Interest Review Task Force for review of conflict of interest. The Task Force will give the response to the staff to be discussed in the latest IRB full board meeting regarding whether it can be approved or not.

5.4.1.2 審查結果為「須修正」，則將審查意見通知計畫主持人，計畫主持人補件（回覆審查意見）天數為 7 個日曆天，說明是否依建議迴避、減免或撤除潛在的利益衝突。計畫主持人之回覆意見提交予利益衝突審議小組審閱後，將小組決議交付秘書處行政人員，排入最近一次 IRB 大會審查，以決定是否通過。

5.4.1.2 If the result is “Modifications required as suggested, ”the suggestions will be sent to the principal investigator, the PI should respond within 7 calendar days to the Task Force whether he will avoid, reduce or remove the potential conflict of interest according to the suggestions. The Task Force will give the response to the staff to be discussed in the latest IRB full board meeting regarding whether it can be approved or not.

5.4.2 利益衝突審議小組依據以下考量，決議是否有利益衝突，並做相關處置建議並提報人體研究倫理審查委員會，包括：

5.4.2 The Conflict of Interest Review Task Force convenes to deliberate on a potential conflict of interest case, make resolutions, give suggestions and report to the IRB regarding the following issues:

5.4.2.1 臨床試驗/研究的學術價值。

5.4.2.1 The academic value of the study.

5.4.2.2 臨床試驗/研究對受試(檢、訪)者可能產生的風險性有多大。

5.4.2.2 The level of risk that the study may present to the subjects.

5.4.2.3 所持有之財務利益的種類以及金額或非財務關係之性質。

5.4.2.3 The type and amount of the financial interest or the nature of the non-financial relationship.

5.4.2.4 財務利益/非財務關係是否會影響該臨床試驗/研究的執行與其結果，或該試驗/研究可能影響財務利益所得/非財務關係。

5.4.2.4 Whether the financial interest or non-financial relationship will affect the implementation and the result of the study, or whether the study may affect the income from the financial interest or non-financial relationship.

5.4.2.5 涉及利益衝突的人員或本院本身，是否具有獨特的能力、經驗、設備等背景，是執行該臨床試驗/研究之不二人選。

5.4.2.5 Whether the person involved in the conflict of interest or TCVGH has unique ability, experience or equipment, and is thereby the only option to conduct the study.

5.4.2.6 持有顯著財務利益/非財務關係的主管之職權與此臨床試驗/研究及相關試驗/研究人員的關係。

5.4.2.6 The job-related duties of the supervisor who has significant financial interest or non-financial relationship, and how the duties relate to the study and the research personnel.

5.4.3 利益衝突審議小組針對利益衝突的案件得做出以下處置建

議：

5.4.3 The Conflict of Interest Review Task Force gives the following suggestions for handling conflict of interest cases:

5.4.3.1 撤除所有顯著財務利益/非財務關係。

5.4.3.1 Remove all significant financial interests or non-financial relationships.

5.4.3.2 公開揭露所持有之顯著財務利益/非財務關係

5.4.3.2 Publicly disclose the significant financial interests or non-financial relationships.

5.4.3.3 設置獨立之資料安全監督機制。

5.4.3.3 Establish an independent data safety monitoring mechanism.

5.4.3.4 涉及利益衝突人員不參與本臨床試驗/研究或迴避部分研究，例如計畫主持人避免執行取得受試(檢、訪)者同意或資料分析等工作。

5.4.3.4 Personnel with conflict of interest shall stop participating in all or part of the study; for example, the principal investigator, in case of conflict of interest, shall not be involved in obtaining subjects' consent or analyzing data.

5.4.3.5 涉及利益衝突的主管迴避行使職權督導該臨床試驗/研究計畫之執行以及其相關試驗/研究人員。

5.4.3.5 The supervisor with conflict of interest shall not execute his/her power to supervise the conduct of the study or to supervise the research personnel.

5.4.3.6 每年向利益衝突審議小組報告，是否遵循建議，迴避或減免利益衝突。

5.4.3.6 An annual report shall be submitted to the Conflict of Interest Review Task Force detailing if suggestions have been followed to avoid or reduce conflict of

interest.

5.4.4 人體研究倫理審查委員會參考利益衝突審議小組之建議，決定是否通過試驗/研究計畫或核准試驗/研究計畫繼續執行，並確認是否符合試驗/研究委託機構以及主管機關的通報規定。

5.4.4 Based on the suggestion made by the Conflict of Interest Review Task Force, the IRB decides whether to pass the trial/study protocol or approve trial/study protocol to be continued, and verify whether it complies with the reporting requirements defined by the sponsor and competent authority.

5.5 監測利益衝突處置及違規處置(COI monitoring)

5.5 Conflict of Interest (COI) Monitoring

5.5.1 落實監測機制，以及顯著財務利益衝突違規之處置。

5.5.1 The purpose of COI Monitoring is to implement the monitoring mechanism to handle cases of conflict of significant financial interest.

5.5.2 利益衝突審議小組審查涉及利益衝突的人員計畫執行期間之年度報告，確認是否確實遵循利益衝突處置建議，迴避或減免利益衝突。

5.5.2 The Conflict of Interest Review Task Force shall review the annual report submitted by the personnel with a conflict of interest in the course of the study and confirm if suggestions made by the Task Force have been followed to avoid or reduce the conflict of interest.

5.5.3 利益衝突審議小組將不定期稽核主持人是否確實遵循利益衝突處置建議，迴避或減免利益衝突，並將結果陳報本會。

5.5.3 The Conflict of Interest Review Task Force shall conduct an audit periodically to verify if the principal investigator has followed the suggestions made by the Conflict of Interest Review Task Force to avoid or reduce a conflict of interest; the result of the audit shall be reported to the IRB

Board Meeting.

5.5.4 若違反利益衝突處置計畫者，將提大會討論並依本會「IRB-本會-工作常規-2016 試驗偏離背離的處理管理程序書」進行相關懲處。

5.5.4 Any case of violating IRB resolutions or regulations regarding conflict of interest shall be submitted to the IRB Board Meeting for discussion; disciplinary actions shall be taken in conformance with the SOP titled "IRB-Regulations of Operation-2016-SOP for Protocol Deviation/Violation."

5.5.5 需立即進行教育訓練(Educational Training)的情況：

5.5.5 Educational Training is required immediately when:

5.5.5.1 財務利益衝突政策有某種程度上的修訂，使對研究人員的要求產生改變。

5.5.5.1 Training shall be provided when changes to the policy on conflict of financial interest lead to changes of the requirements for research personnel.

5.5.5.2 研究人員未配合財務利益衝突的政策和程序。

5.5.5.2 Research personnel shall be educated about conflict of interest policy or procedure when they do not comply with related policies and procedures.

5.5.5.3 新的研究人員於線上系統提交案件給本會審查時，系統將會自動帶出財務利益衝突的相關說明供參閱。

5.5.5.3 When new research personnel submit a protocol to the IRB via the online system, the system will automatically display relevant information regarding conflict of financial interest for reference.

5.6 利益衝突審議小組將定期評估受試者保護中心提供之年度「機構利益衝突」相關資料，若有涉及利益衝突之情況，將提報人體研究倫理審查委員會。

5.6 The Conflict of Interest Review Task Force will regularly

evaluate the annual "Institutional Conflict of Interest" information provided by the Human Research Protection Center, and if there is a conflict of interest, it will be reported to IRB.

5.7 紀錄保存(Record Keeping)

5.7 Records Retention

相關人員應依據如下規定，妥善保存各項紀錄。

Relevant personnel should keep all records carefully following the guidelines below.

編號 Document Number	紀錄名稱 Name of Document	保存地點 Retention Location	保存期限 Retention Period
1	顯著財務利益暨非財務關係申報表 (與 PTMS 表格一致) Statement of Disclosure of Significant Financial Interests and Non-financial Relationships (same as the form on PTMS)	IRB 辦公室 IRB Office	臨床試驗/研究計畫結束後 15 年 15 years after the study
2	利益衝突審查決議文件 Documents on the Resolution of Conflict of Interest Cases	IRB 辦公室 IRB Office	臨床試驗/研究計畫結束後 15 年 15 years after the study

6.附件

無。

6. Appendix

None.