# 臨床試驗合約書

# Clinical Trial Contract

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| **立合約書人（甲方）：**高雄醫學大學<br>法定代理人：　　校 長<br>**Party (A):** Kaohsiung Medical University<br>Legal Representative:　Principal |
| **立合約書人（乙方）：**財團法人私立高雄醫學大學附設中和紀念醫院<br>法定代理人：　　院 長<br>**Party (B):** Kaohsiung Medical University Chung-Ho Memorial Hospital<br>Legal Representative:　Superintendent |
| **立合約書人（丙方）：**<br>**Party (C):** |
| **立合約書人（丁方）：**<br>法定代理人：<br>**Party (D):**<br>Legal Representative: |
| **計畫名稱 Protocol Title:** |
| **計畫編號 Protocol No.:** |

茲因丁方委託乙方醫師＿＿＿＿＿＿＿＿＿＿（丙方）就丁方之下列計畫進行人體臨床試驗，各當事人特訂立此合約，以資遵循，甲方並授權乙方執行本合約。丁方得另行簽訂書面協議委任 Contract Research Organization (CRO) 擔任試驗委託者之

授權代表及代理人從事與本協議有關之義務轉讓與功能。
Whereas Party D contracts Party B's physician, _____ (Party C), to perform Party D's human clinical trial under the following protocol (hereinafter referred to as the "Study"), now, therefore, all parties sign the Contract to be bound by all parties hereto and Party A authorizes Party B to perform the Contract accordingly. Party D may engage a Contract Research Organization (CRO) on behalf of Party D for the purposes of transferring certain duties and functions in connection to this Contract as its authorized representative and agent under a separate written Contract.

**1. 人體試驗之內容**
**Contents of Trial**

(1) 本試驗計畫之內容及執行進度，詳見本試驗之「試驗計畫書」。
The contents and progress of the Study are detailed in "Clinical Trial Protocol" of this Contract.

(2) 本試驗計畫由乙方之_____醫師(丙方)作為計畫主持人。
Party B's physician, Dr. _____ (Party C), shall act as the principal investigator of the Study.

(3) 丙方應依照「試驗計畫書」所載之內容執行本試驗計畫。如需變更試驗內容或進度，應事先獲得丁方之同意，並應取得乙方人體試驗審查委員會核准，如經行政院衛生福利部列管之案件須經中央衛生主管機關之核准。
Party C shall perform the Study in accordance with the "Clinical Trial Protocol". Any change of the contents or progress of the Study shall be subject to prior consent of Party D and shall be approved by Party B's Institutional Review Board (IRB), and also to the central government competent health authority's approval if the Study refers to the case controlled by Ministry of Health and Welfare, Executive Yuan.

(4) 乙方與丙方確保僅任用受過適當培訓且合格的人員，擔任協同主持人或研究人員。
Party B and Party C will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Study as sub-investigators or research staff.

(5) 本試驗計畫之執行品質，應符合試驗計畫書規定並經各當事人同意之標準，丁方並得隨時在法令許可範圍內派員查核試驗記錄及試驗數據之真確性，或要求乙方提供試驗紀錄以供查核，乙方不得拒絕，但不得影響乙方之正常作業。

The performance of the Study shall comply with the Clinical Trial Protocol and standards agreed by all parties hereto in quality. Party D may send its personnel to audit the Study record and accuracy of Study data, insofar as it is permitted by laws, from time to time, or requests Party B should provide the Study record for the purpose of audit. Party B shall not withhold its consent to the audit, provided that Party B's normal operation will not be affected accordingly.

(6) 丙方執行本試驗計畫，應遵守中華民國相關之法令及規範，在施行人體試驗之前，並須使受試者簽妥經丙方、乙方人體試驗審查委員會與丁方核准之「受試者同意書」(其格式與內容見本合約書附件)，並將已簽妥之「受試者同意書」副本及任何給予受試者或其法定代理人之其他必要書面資訊歸檔，以利丁方或其指定人員為監督臨床試驗之目的而查閱之。

Party C shall conduct the Study in accordance with applicable laws and regulations of the Republic of China, and shall have the Study subjects sign the "Informed Consent Form" in a form approved by Party C, IRB/EC of Party B and Party D before the conduct of the Study, (the form and content of such Informed Consent are specified in the appendix of the Contract), and archive the copies of signed "Inform Consent Form" and any other written information provided to the subjects or their legal representatives so as to permit Party D or its designated personnel to audit the Study for the purpose of supervision of the Study.

## 2. 試驗計畫執行期間
## Term of Study

本試驗計畫預計自西元_____年___月___日開始執行至西元_____年___月___日止，為期____月。如計畫執行有所變動(延長/縮短/變更)，應經各當事人書面同意。

The Study shall commence from MM/DD/YY until MM/DD/YY, a total of _____ months. Any changes of the Study (extension/shortening/amendment) shall be subject to written consent of all parties hereto.

## 3. 人體試驗委員會之核准
## IRB Approval

(1) 丙方應於研究開始執行本試驗計畫前，取得乙方人體試驗審查委員會（必要時並應取得中央衛生主管機關）之核准，丁方並應提供必要之協助。

Party C shall obtain the approval of Party B's IRB (and the central government competent health authority's approval, if necessary,) before conducting the Study, and Party D shall provide any necessary assistance.

(2) 丙方在未取得前項核准前，不得對任何人進行任何本試驗計畫中之人體試驗。
Party C shall not perform the human clinical trial on any person under the Study before obtaining the approval referred to in the preceding paragraph.

**4. 主持人手冊及相關資料之提供**
**Investigator's Brochure and Relevant Information**

(1) 丁方應於本試驗計畫開始前，提供丙方關於本試驗之主持人手冊，以說明試驗項目（包含藥品、器材及其使用方法等）之已知特性。
Party D shall provide Party C with the Investigator's Brochure to explain existing characteristics of the Study elements (including drugs, medical devices and method of use, etc.) prior to the conduct of the Study.

(2) 丙方應於計畫開始執行前，詳細研讀試驗計畫書與主持人手冊之內容。
Party C shall carefully read the Clinical Trial Protocol and Investigator's Brochure before conducting the Study.

(3) 丁方一旦發現與試驗項目有關之重要資訊時，應立即更新主持人手冊，並以書面告知乙方與丙方。
Upon awareness of any important information related to the Study, Party D shall update the Investigator's Brochure immediately and advise Party B and Party C in writing.

(4) 丁方自其他試驗機構所獲得之與本試驗計畫內容相關之試驗數據與資料，應提供予丙方。
The Study data and information related to the Study obtained by Party D from other institutions, if any, shall be provided to Party C.

(5) 丁方應以書面方式，向丙方提供臨床試驗所用試驗藥物之所有相關資訊，及足以取得所有受試者或其法定代理人之知情同意，以及 IRB/IEC 核准所必要或需要之所有其他資訊。丙方應確保所有受試者或其法定代理人充分知悉上述資訊及臨床試驗細節。本項適用於任何關係受試者或其法定代理人知情同意事宜之重要新資訊。
Party D shall provide Party C with all information related to the investigational product being used in the conduct of the Study and all other information necessary

to obtain informed consent from all subjects and their legal representatives, in addition to any other information required or needed by IRB/IEC for approval, in writing. Party C shall ensure that all of the subjects and their legal representatives have full knowledge of said information and details about the Study. This paragraph shall be applied whenever any important new information becomes available that may be relevant to the informed consent of the subjects or subjects' legal representatives.

(6) **丁方或其代理人負責臨床試驗之資料與安全監測時，丁方應提供臨床試驗資料與安全監測報告給乙方、丙方及乙方人體試驗審查委員會**。(參照 AAHRPP 評鑑基準第 I.8.C 條規定)
When Party D or its agent is responsible for the Study data and safety monitoring, Party D shall provide the Study data and safety monitoring report to Party B, Party C, and Party B's IRB.

(7) 臨床試驗結束後，如發現有直接影響受試者安全之資訊，丁方應通知乙方、丙方及乙方人體試驗審查委員會。(AAHRPP 評鑑基準 1.8.E)
Upon awareness of any information affecting the subjects' safety directly after the end of the Study, Party D shall notify Party B, Party C, and Party B's IRB.

## 5. 保密義務
**Non-Disclosure**

(1) 甲、乙、丙方應對丁方給予之任何機密資訊，或在研究範圍內所得之數據加以保密，未經丁方書面同意之前，不得向第三者揭露。但有下列情況之一者，不在此限：
Party A, Party B and Party C shall keep any confidential information provided by Party D or the data generated from the Study in confidence and shall not disclose to any third party without Party D's prior written consent, unless in any of the following circumstances:

I. 屬於公眾所知悉之知識。
Where the information falls in the public domain;

II. 甲、乙、丙方可證明於丁方揭露前甲、乙、丙方已持有或知悉之資訊。
Where the information already possessed or known by Party A, Party B and Party C prior to Party D's disclosure as demonstrated by Party A, Party B and Party C;

III. 非因甲、乙、丙方過失所致，而成為公眾所知悉之知識。
Where the information falls in the public domain through no fault of Party A, Party B or Party C;

IV. 甲、乙、丙方由具有合法權利之第三人處取得之資訊。
Where the information is accessed by Party A, Party B and Party C from a third party with valid rights;

V. 甲、乙、丙方受法令強制公開之資訊。
Where the information is required to be disclosed by Party A, Party B and Party C pursuant to laws.

(2) 前項所稱機密資訊係指丁方為落實執行本試驗計畫而向甲方或乙方或丙方透露本身擁有的一切相關資訊，包括但不限於計畫主持人資料、計畫書、報告、訊息、圖形、處方及製程等（以下簡稱機密資訊）。
The confidential information referred to in the preceding paragraph means Party D's information disclosed by Party D to Party A, Party B or Party C in order to conduct the Study, including but not limited to, the principal investigator's information, protocol, report, message, drawings, prescriptions, and process, etc. (hereinafter referred to as the "Confidential Information").

(3) 除口頭揭露或難以標示上述「機密」等字樣之資料，丁方應於揭露予甲方及/或乙方及/或丙方前，應先於資料上標示「機密」、「保密」、「密」等字樣，以利甲方及/或乙方及/或丙方辨明為機密資訊。
Except the information disclosed verbally or unlikely to be marked "confidential", Party D shall mark "confidential", "privileged" and "secret" on the information prior to disclosing to Party A, Party B and/or Party C to help Party A, Party B and/or Party C identify the confidential information.

(4) 以口頭方式揭露或難以標示上述「機密」等字樣之資料，丁方應於揭露時明示為機密資訊，並於首次揭露十日內以書面方式註明為機密資訊後交予甲方及/或乙方及/或丙方。
With respect to the aforesaid information disclosed verbally or unlikely to be marked as "confidential", Party D shall expressly identify such information as Confidential at the time of disclosure, and deliver the same identified as "confidential information" in writing to Party A, Party B and/or Party C within ten(10) days upon the first disclosure.

**6. 監測、監督、稽核**

**Monitoring, Supervision and Audit**

(1) **丁方應對臨床試驗進行安全監測，如發現對受試者有安全疑慮及影響臨床試驗之執行時，應立即通報乙方人體試驗審查委員會、受試者保護中心、乙方及丙方。**(參照 AAHRPP 評鑑基準第 I.8.B 條規定)

Party D shall monitor the clinical trial safety, and report to Party B's IRB, Human Research Protection Center, Party B and Party C immediately upon awareness of any concerns about the safety of Study subject and affecting the conduct of the Study.

(2) 丁方應依相關法律規定之試驗委託者義務，監督臨床試驗。丁方、其指定之任何共同研究者(包括但不限於選定 CRO，以下統稱「共同研究者」)及/或其指定人員(例如，外包商/顧問)，應於臨床試驗期間持續定期監督。監督得包括但不限於審查及檢查乙方與丙方實施臨床試驗所需之處所，及檢查、查閱及/或複印與臨床試驗相關之資料、記錄與工作產物。丁方應至少每隔四到六週，或於乙、丙、丁三方同意之間隔期間，於事前合理通知乙方、丙方後，於乙、丙、丁三方協議之時間進行監督訪查。乙方與丙方應提供丁方或其指定人員進行該等訪查所需之一切協助。

Party D shall be obligated to supervise the Study as the Sponsor pursuant to applicable laws and regulations. Party D and its designated collaborator (including but not limited to, the CRO, hereinafter referred to as the "collaborator") and/or their designees (e.g., contractors/consultants) shall continue to supervise the Study periodically in the duration of the Study, including but not limited to, exanimating and inspecting the premises required by Party B and Party C to perform the Study, and checking, inspecting and/or reproducing any information, record and product related to the Study. Party D may conduct an on-site visit to supervise the Study at a minimum of 4-6 week intervals, or at such other intervals mutually agreed by Party B, Party C and Party D, by giving a reasonable notice to Party B and Party C prior to the time limit agreed by Party B, Party C and Party D. Party B and Party C shall provide Party D or its designees with all assistances required by Party D or its designees to conduct the visit.

(3) 經事前合理通知乙方與丙方後，丁方、共同研究者及/或其指定人員 (例如，外包商/顧問) 得於彼此均可接受之時間，定期進行藥品優良臨床試驗準則 (GCP) 之稽核，包括但不限於審查及檢查乙方與丙方實施臨床試驗所需之處所，及檢查、查閱及/或複印臨床試驗之資料、記錄與工作產物，乙方與丙方

應提供丁方或其指定人員執行該等稽核所需之一切協助。乙方與丙方亦應於臨床試驗主管機構要求時，允許該等機關監督或檢查臨床試驗之執行狀況。乙方與丙方一旦接獲上述要求或知悉主管機構採取任何其他有關臨床試驗之行動，應立即通知丁方，丁方有權於適用法律不禁止之範圍內，針對該等機構提出之要求或作為全權採取和掌控相關因應措施。

Upon giving a reasonable prior notice to Party B and Party C, Party D, collaborator and/or its designees (e.g., contractors/consultants) may conduct an audit under the Good Clinical Practice periodically within the time limit acceptable by each other, including but not limited to, reviewing and checking the premises required by Party B and Party C to perform the Study, and checking, inspecting and/or reproducing any information, record and product related to the Study. Party B and Party C shall provide Party D or its designees with all assistances required by Party D or its designees to conduct the audit. Upon request of the competent authority in charge of the Study, if any, Party B and Party C shall allow the authority to supervise or check the status of the Study. Upon receipt of said request or awareness of any other actions taken by the authority against the Study, Party B and Party C shall notify Party D immediately. Party D shall, at its option and to the extent not prohibited by applicable law, have full conduct and control of any dealings in respect of any request or action required by such bodies.

**7. 公開發表**
**Publication**

(1) **本試驗計畫執行之研究結果，甲、乙、丙方經丁方審閱並同意後，得公開發表之。但基於衛生主管機關之法令要求而公開者，不在此限。**(參照 AAHRPP 評鑑基準第 I.8.D 條規定)

The Study result may be published by Party A, Party B and Party C upon Party D's review and approval, unless it is required to be published by laws and/or regulations from the health authorities.

(2) 丁方如因本試驗計畫申請專利或其他智慧財產權保護上之必要，得要求甲、乙、丙方延遲公開發表研究結果，但不得超過丁方收到該擬發表之內容時起____個月內，甲方、乙方及丙方無正當理由不得拒絕。

Party D may request Party A, Party B and Party C to postpone publishing the Study result in order to protect the patent application or other intellectual property rights

under the Study, if any, provided that the postponement shall be no more than _____ month(s) from the date that Party D receives the contents to be published. Party A, Party B and Party C shall not unreasonably withhold their consent.

**8. 藥品、器材及其他物品之使用與返還**
**Use and Return of Drug, Device and Other Goods**

(1) 關於本試驗計畫之執行，丁方應提供丙方試驗所需之藥品、器材及其他相關財物。該藥品、器材及其他相關財物，丙方僅得供本試驗計畫之目的而使用，不得轉作其他用途。
Party D shall provide Party C with the drug, device and other materials, required for the conduct of the Study. Such drug, devices shall not be used by Party C for any purpose other than the conduct of the Study.

(2) 本試驗計畫完成或終止後，前項剩餘之物，除另有約定外，丙方應歸還丁方。
Upon completion or termination of the Study, Party C shall return the remaining drugs, devices or materials, if any, to Party D, unless otherwise agreed herein.

**9. 付款**
**Payment**

(1) 丁方應按照本合約書之預算表所列之經費、付款方式與付款期限，依乙方規定辦理支付。
Party D shall, in accordance with the budget, payment method and payment term detailed in the Payment Schedule of this Contract, fulfill the payment in accordance with Party B's indication.

(2) 本試驗相關之一切檢查與檢驗費用，均應由丁方負責支付。
Party D shall be responsible for all examination and laboratory fees in connection with the Study.

**10. 計畫資料、成果之歸屬**
**Ownership of Study Data and Result**

(1) 除另有約定外，丙方因執行本試驗所獲得之試驗數據及文件，由甲、乙、丙方與丁方共有。但受試者之病歷資料歸乙方所有。各當事人各自現有之發明或

技術為其個別所有之財產，不受本合約之影響。
Unless otherwise agreed herein, the trial data and documents derived by Party C from the Study shall be owned by Party A, Party B, Party C and Party D jointly, provided that the subjects' medical records shall be owned by Party B. Nothing set forth in this Contract shall affect the ownership of any invention or know-how created by either party and shall remain the ownership of either party respectively.

(2) 前項試驗數據及文件，於本試驗計畫終止後，丙方應依藥品優良臨床試驗準則(GCP)第 101 條規定，保留本試驗計畫之原始資料。
Party C shall retain the original Study data and documents referred to in the preceding paragraph in accordance with Article 101 of the GCP after termination of the Study.

(3) 丙方因執行本試驗所獲致之研究成果，其專利申請權與專利權，歸丁方所有。但另有約定者，依其約定。
The patent application right and patent right in the study result generated from the Study performed by Party C shall remain vested in Party D, unless otherwise agreed herein.

(4) 甲、乙、丙方於學術期刊所刊載與本試驗相關之論文，除另有約定外，該論文著作權歸屬甲、乙、丙方所有。
Copyright in the paper published by Party A, Party B and Party C with respect to the Study in any academic publications shall remain vested in Party A, Party B and Party C, unless otherwise agreed herein.

## 11. 報告義務
## Obligation to Report

(1) 丙方應按照試驗計畫書所定之期間，向丁方報告試驗進度及研究情況。丁方亦得隨時詢問丙方進度及研究情況。
Party C shall report the progress and status of the Study to Party D within the time limit prescribed in the clinical trial protocol. Party D may inquire Party C for the progress and status from time to time.

(2) 如人體試驗進行中有發生病患傷害或死亡等嚴重不良事件，丙方應立即告知丁方，使其知悉。丁方對於非預期之嚴重不良反應，應依中央衛生主管機關規定立即通報中央衛生主管機關與乙方人體試驗審查委員會。
Party C shall immediately (within 24 hours) inform Party D of any serious adverse

event, which leads to subjects' injuries or deaths during the course of the Study. Party D shall immediately report any unexpected serious adverse reaction to central competent health authorities and the Institutional Review Board (IRB) of Party B in compliance with the regulations of the central competent health authorities.

**12. 合約之終止**

**Termination of Contract**

(1) 丙方執行本試驗，因故意或過失違反本合約書或本試驗計畫書之約定時，丁方得以書面通知丙方限期改善(不得少於 15 日)，如丙方逾期仍未改善，丁方得以書面通知其他方終止本合約。

Where Party C conducts the Study in violation of the Contract or the Clinical Trial Protocol intentionally or negligently, Party D may send a written notice demanding that Party C should rectify the misconduct within specific time limit (no less than 15 days). Where Party C fails to cure the breach within said time limit, Party D may notify the other parties in writing to terminate the Contract.

(2) 丁方若有違反本合約書約定時，乙方、丙方得以書面通知丁方限期改善(不得少於 15 日)，丁方逾期未改正，乙方、丙方得終止本合約。

Where Party D violates the Contract, Party B and Party C may send a written notice demanding that Party D should rectify the misconduct within specific time limit (no less than 15 days). Where Party D fails to cure the breach within said time limit, Party B and Party C may terminate the Contract.

(3) 第(一)項情形，丁方除已支付之費用外，無需再對乙方支付任何費用，丁方亦不得請求乙方及/或丙方退還其已支付之費用。

In the circumstances referred to in Paragraph (1), except the already paid amount, Party D shall not pay any other expenses to Party B, and Party D shall not request refund of payment which already made by it against Party B and/or Party C.

(4) 除第(一)項之情形外，各當事人均得在本試驗計畫執行期限內，以書面於三十日前通知其他方當事人後，提前終止本合約。惟倘係丙方以本項約定終止時，乙方得提出新任計畫主持人，經丁方同意後，由新任計畫主持人簽署本合約書後，繼續本試驗計畫之執行。

Except the circumstances referred to in Paragraph (1), either party may terminate the Contract earlier by giving a 30-day prior written notice to the other parties in

the duration of the Study, provided that where Party C terminates the Contract according to the covenant herein, Party B may recommend a new principal investigator, and the new principal investigator may continue to conduct the Study after signing the Contract, upon Party D's prior approval.

(5) 因第(二)項致合約終止，或丁方依第(四)項終止合約，或係基於不可歸責於乙方之事由致合約終止，丁方除已支付之費用外，尚須按照已完成之進度比例，支付費用予乙方，對乙方或丙方因執行本試驗計畫負擔之債務亦應償還。
Where the Contract is terminated due to the circumstances referred to in Paragraph (2), or Party D terminates the Contract pursuant to Paragraph (4), or the Contract is terminated due to circumstances not attributed to Party B, in addition to the expenses already paid, Party D shall make the remaining payment to Party B pro rata in accordance with the progress of the Study. Party D shall also be responsible for the debt owed by Party B or C as incurred from the implementation of the Study.

(6) 丙方於合約終止生效時，應停止招募受試者並停止試驗計畫之執行，如有違反，丁方對因此而生之損害不負賠償責任，但不影響對受試者的良好醫療照護。
After termination of the Contract takes effective, Party C shall cease to enroll subjects and conduct the Study; If Party C violates such provision, Party D shall not be liable for any damages arising therefrom, provided that the subjects' good medical care and treatment shall not be affected.

(7) 任一方終止本合約均不影響各當事人在終止生效前所應負之權利及義務。
Each party's right and obligation accruing prior to the valid termination shall remain unaffected by either party's termination of the Contract.

**13. 損害賠償**
**Damages**

(1) **受試者因參與本試驗計畫而受之損害，如乙方或丙方或相關臨床人員，於執行計畫時已遵循試驗計畫書之步驟，由丁方負損害賠償責任；乙、丙方因治療受試者所支出之費用，亦由丁方負擔。丁方同意若有因本試驗計畫導致受試者受有傷害或損害，致甲方或乙方或丙方因此須對他人負賠償責任時，丁方應對此所生之治療或其他相關費用、支出、責任，及一切損害及損失負責(包括但不限於精神賠償金、法院判決金額、律師費用及經丁方同意由甲方或乙**

**方或丙方與受試者和解所支付之金額，但丁方不得不合理拒絕此同意)**。(參照 AAHRPP 評鑑基準第 I.8.A 條規定)

The damages caused to the subjects for participation in the Study, if any, shall be borne by Party D, insofar as Party B or Party C or relevant study personnel has already complied with the procedure under the Clinical Trial Protocol when conducting the Study. The expenses incurred by Party B and Party C for treatment of the subjects shall be borne by Party D. Party D agrees that where the Study results in harm or damage to the subjects and thereby Party A, Party B or Party C shall be liable for damages to another party, Party D shall be liable for all the treatment expenses, other related expenses, costs, liabilities, damages and losses derived therefor (including but not limited to, psychological damage compensation, amount of damage concluded by court, attorney fees, and the damages payable to the subjects upon settlement of Party A, Party B or Party C with the subjects upon Party D's consent which Party D shall not withhold without justified reasons).

(2) 受試者因參與本試驗計畫而致之損害，如係基於丙方或相關臨床人員，於執行計畫時之故意、過失，或未遵循試驗計畫書之規定所致者，由丙方負損害賠償責任。

Where the damage suffered by any subject for participation in the Study is caused by Party C or related research personnel intentionally or negligently when conducting the Study, or failure to comply with the clinical trial protocol, Party C shall be liable for it.

(3) 除第（二）項之情形由乙方及丙方對受試者負賠償責任外，甲、乙、丙方對丁方之任何損害或損失、利益損失、利潤損失均不負任何賠償責任。

Neither Party B nor Party C shall be liable for any damages or losses, loss of interests or loss of profits of Party D, except for the situation where Party B and Party C shall be solely responsible for indemnification to the subjects, as specified in the preceding paragraph (2).

## 14. 保險義務
## Obligation of Insurance

丁方對於本試驗，應向保險公司投保並維持足夠之責任保險以擔保各當事人足以負擔相關法律責任，並應以丁方為要保人，各當事人為被保險人。未投保者，須經乙方同意。

With respect to the Study, Party D shall purchase and maintain sufficient liability insurance to cover the legal liability to be borne by either party. Party D shall act as the proposer and the other parties shall be named as the insured. Party D shall not refuse to acquire such insurance without Party B's prior consent.

**15. 照護義務**

**Obligation to Care**

(1) **合約終止後，乙方認為有繼續對受試者為必要之醫療照護，以確保受試者之利益者，丁方同意繼續無償提供藥品、器材或負擔相關費用。**(參照 AAHRPP 評鑑基準第 I.8.A 條規定)

Where Party B considers that it should be necessary to provide the subjects with required medical care to ensure the subjects' interest upon termination of the Contract, Party D agrees to continue providing the drugs and devices free of charge or bear the related expenses.

(2) 第十三條之規定於前項情形準用之。

The requirements provided in Article XIII herein shall apply to the circumstances referred to in the preceding paragraph.

**16. 其他**

**Others**

**根據 ICH GCP 5.1 (品質保證與品質管制) ，丁方應負責以書面標準作業程序 (SOP) 執行並維持品質保證與品質管制系統，以確保本試驗之執行及資料之產生、記錄和報告均能依據試驗計畫書、GCP，以及適用之法規要求。丁方應對本試驗資料之品質、安全與完整性負最終責任。丙方應依據 ICH GCP 4.9.1 確保個案報告表和所有需要向丁方報告之資料的精確性、完整性、易讀性和時間性。所有當事人皆需確保研究數據可靠、有效，研究結果在統計上準確無誤，合乎倫理及沒有偏見。**(JCI 評鑑條文 HRP.3)

In accordance with ICH GCP 5.1 (Quality Assurance and Quality Control), Party D is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that Study is conducted and data are generated, documented (recorded), and reported in compliance with the Protocol, GCP, and the applicable regulatory requirements. Party D should have the ultimate responsibility for the quality and integrity of the Study data. Party C should ensure

the accuracy, completeness, legibility, and timeliness of the data reported to the Parry D in the CRFs and in all required reports based on ICH GCP 4.9.1. The Parties each ensure that the research data are reliable and valid and the results and reporting are statistically accurate, ethical, and unbiased.

**17. 準據法**

**Governing Law**

本合約以中華民國法律為準據法。

The Contract shall be governed by the R.O.C. laws.

**18. 管轄法院**

**Jurisdictional Court**

因本合約所生之爭議，各當事人合意以臺灣高雄地方法院為第一審管轄法院。

All parties agree that the dispute arising from the Contract, if any, shall be submitted to the jurisdiction of the Taiwan Kaohsiung District Court as the first instance.

本合約以中英文並列簽訂，如有任何牴觸或不一致，以中文版本為準。

This Contract is written in Chinese and in English. In case of any conflict or discrepancy between the two versions, the Chinese version shall govern.

**立合約書人（甲方）：**高雄醫學大學

法定代理人：　　校 長

地址：

日期（西元年/月/日）：

**Party (A):** Kaohsiung Medical University

Legal Representative:　Principal

Address:

Date (MM/DD/YYYY):

**立合約書人（乙方）：**財團法人私立高雄醫學大學附設中和紀念醫院

法定代理人：　　院 長

地址：

日期（西元年/月/日）：

**Party (B):** Kaohsiung Medical University Chung-Ho Memorial Hospital

Legal Representative:　Superintendent

Address:

Date (MM/DD/YYYY):

**立合約書人（丙方）：**　　(計畫主持人)

地址：

日期（西元年/月/日）：

**Party (C):**　　(Principal Investigator)

Address:

Date (MM/DD/YYYY):

**立合約書人（丁方）：**　　（試驗委託者）

法定代理人：

地　　址：

統一編號：

日期（西元年/月/日）：

**Party (D):**　　(Sponsor)

Legal Representative:

Address:

GUI No.:

Date (MM/DD/YYYY):