**臺中榮民總醫院**

**Taichung Veterans General Hospital**

**臨床試驗契約書**

**Clinical Trial Agreement**

立契約書人臺中榮民總醫院(以下簡稱甲方)及○○○○○○○○○公司(以下簡稱乙方)為乙方委託甲方實施臨床試驗事宜，茲訂定本契約，以昭信守：

This Clinical Trial Agreement is entered into by and between Taichung Veterans General Hospital (TCVGH, “Institution,” hereinafter referred to as “Party A”) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Sponsor,” hereinafter referred to as “Party B”). Collectively Party A and Party B may be referred to as “the Parties,” WHEREAS, Party B wants to enlist the assistance of Party A to conduct clinical research (“Study”); WHEREAS, Party B desires to provide funding and drug/devices to enable Party A to conduct the Study;NOW, in consideration of the mutual promises and covenants contained in this Agreement, the Parties therefore agree as follows.

壹、甲方接受乙方委託，茲就(試驗名稱)及(試驗藥品或生技製品或醫療器材名稱)實施臨床試驗。並指派其○○科○○○醫師（以下簡稱「試驗主持人」）進行本臨床試驗。 Party A will conduct the Study as described in the Study Protocol titled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Drug,” “Device,” or “Product”). The Study will be completed under the direction of Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Principal Investigator, hereinafter referred to as ‘PI”) of the Division of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ assigned by Party A.

貳、乙方保證其所提供臨床試驗之藥品(或生技製品或醫療器材)，完全符合法令規定，且其製造、包裝、標示均符合優良藥品(或生技製品或醫療器材)製造標準之規定及現時科技與專業水準。該藥品(或生技製品或醫療器材)不論是否為乙方所設計、製造或輸入，乙方均願依藥品優良臨床試驗準則對受試者負擔設計者、製造者或輸入者之責任。  
乙方應負責為臨床試驗之藥品(或生技製品或醫療器材)及受試驗者投保產品責任險或臨床試驗相關保險。 Party B will ensure that the Drug (Product or Device) provided for the Study complies with all applicable laws and regulations and that the manufacturing, packaging, and labeling of the Drug/Product/Device are in conformance with Pharmaceutical Good Manufacturing Practice Regulations and current technological and professional standards. Party B will take full responsibility on behalf of the designer, manufacturer, or importer of the Drug (Product or Device) towards Study Subjects in conformance with the Regulations for Good Clinical Practice regardless of whether Party B is the designer, manufacturer, or importer of the Drug (Product or Device) or not. Party B will provide insurance for all Study Subjects including product liability insurance and other medical insurance necessary for the Study.

参、臨床所需之藥品(或生技製品或醫療器材)及相關費用由乙方負責。計畫經費總額、撥付方式、明細用途及執行期限依照預算明細表(如附件)實施。  
本臨床試驗自 年 月 日開始執行，至 年 月 日為限，得視實際需求經雙方議定後增減之。 Party B will provide Party A with sufficient numbers of Drug (Product or Device) needed for the Study; Party B will pay for all expenses incurred. The total amount of the study budget, payment method, details of the budget, and study implementation time period shall be in accordance with the Study Budget (see Exhibit). The Study Implementation Time Period will be from (Year) (Month) (Day) to (Year) (Month) (Day). Changes to the dates can be made if both Parties agree.

肆、本臨床試驗藥品(或生技製品或醫療器材)限於甲方之臨床試驗主持人使用於本臨床試驗案之受試者，不供其他研究者或機關使用。 The use of the Drug (Product or Device) provided for the Study shall be limited to the usage of the PI assigned by Party A on Study Subjects for the Study; the Drug (Product or Device) shall not be used by any other researcher or institution.

伍、本試驗所產生之案例報告及其他資料(下稱資料)，悉歸試驗委託者所有，試驗委託者得以任何形式利用該資料。 Case reports or other data (hereinafter referred to as “Data”) produced from the Study shall belong to the Sponsor; the Sponsor may use the Data in any way or format.

陸、本試驗所產生及包含於資料內之資訊，其智慧財產權歸試驗委託者所有，但涉及運用院方或計畫主持人技術成果或智慧財產所獲得者，另行協議之。. The intellectual property rights of the Data from the Study shall belong to the Sponsor except for research results arising from using technology or intellectual property of TCVGH or the PI. The ownership of the intellectual property rights in the latter case shall be decided upon mutual agreement of both Parties.

柒、試驗委託者有權發表本試驗所產生之任何資料及資訊，毋須經試驗單位同意。. The Sponsor has the right to publish any data or information arising from the Study without permission from the Institution.

捌、試驗單位對本試驗成果及由試驗委託者提供之背景資料，皆有發表權利，但應於發表前至少六十日送交試驗委託者；若試驗委託者於收到試驗單位提供之資料後有以下之情形，則試驗單位即有權自行發表，惟試驗委託者得因發表內容正確性、資料完整性，及或現存之智慧財產權不得受有侵害等正當之事由，有權要求發表人修改內容，發表人應於修改後再行發表：一、若無任何不可抗力之原因，未於30日內提供回覆意見；抑或未於提出不可抗力原因後45日內回覆意見。二、若該案發表對試驗委託者專利/智慧財產權有相關不利之影響，試驗委託者準備時間90日為限。三、若多中心或單中心試驗案，於完成研究2年後，仍未發表研究成果。四、研究案終止或結束10年以上。 The Institution has the right to publish results from the Study or background information provided by the Sponsor, but the Institution shall submit the manuscript to the Sponsor at least 60 days before the publication. If one of the following situations applies after the Sponsor receives the manuscript from the Institution, the Institution may publish the manuscript. The Sponsor has the right, though, to request the author to revise the manuscript before publishing if there are concerns regarding the accuracy, completeness or intellectual property rights: (1) The Sponsor does not give any response or comments within 30 days without any occurrence of force majeure events; or the Sponsor does not give any response or comments within 45 days upon occurrence of a force majeure event; (2) If the publication of the manuscript has a negative impact on the patent or intellectual property rights of the Sponsor, the Sponsor will be allowed 90 days to respond and give comments to the Institution before the manuscript may be submitted for publication; (3) The Study is a single-center or multicenter study, and no research findings from the Study have been published at least two years after the completion of the Study; (4) The Study was terminated or closed more than ten years ago.

玖、乙方願意為其所提供之藥品(或生技製品或醫療器材)，負責臨床之安全性。如甲方人員依照臨床試驗計畫進行，非因其故意或過失，發生受試者若因參加臨床試驗而造成死亡、傷害、不良反應或其他損害，應由試驗機構及試驗主持人提供專業醫療照護及諮詢，試驗委託者應支付所需之合理醫療費用及損害賠償。並由乙方負全部責任，並確認受試驗者(包括其法定繼承人及其他法定請求權人)對乙方有直接請求權。 Party B shall be responsible for the clinical safety of the Drug (Product or Device) provided for the Study. If death, injury, adverse reaction or other damage to a Study Subject is directly related to the proper performance of any procedure by Party A personnel in accordance with the Protocol, the Institution and the PI shall provide professional care or consultation, and the Sponsor shall pay for reasonable medical expenses or compensation for damage. Party B shall take full responsibility and ensure that the Study Subject (and their heirs and assigns) has the right to make direct claims to Party B.

拾、試驗委託者或其代理人應提供資料及安全監測報告給計畫主持人及人體研究倫理審查委員會；若發現受試者安全有疑慮或有影響臨床試驗執行之狀況，緊急事件應於10個工作天內、例行報告(如:安全監測報告)應於30個工作日內通報本院人體研究倫理審查委員會及受試者保護中心。The Sponsor or its authorized representative shall provide the principal investigator and the IRB with data and safety monitoring reports; if a concern about the safety of the subjects arises or if an event that affects the conduct of the Study occurs, the concern or the event shall be reported to the IRB and the HRPC (Human Research Protection Center) of TCVGH within 10 days in case of an emergency or within 30 days in case of a regular report (e.g. safety monitoring report).

拾壹、雙方因履行本契約而知悉或持有對方一切相關研發資訊，包括但不限於報告、訊息、圖形、處方及製程等，甲乙雙方所屬人員，均應盡善良管理人之注意義務保持其機密性，如有違反情事，應負相關法律責任。甲乙雙方不因本契約期滿或終止而免除所負之保密義務。During the implementation of the Study, both Parties may have access to relevant research data (“Data”) owned by either Party, including but not limited to reports, information, images, formula, and manufacturing process, etc. Personnel from both Parties shall keep the Data confidential and shall be liable legally for any violation against confidentiality. Both Parties shall continue keeping the Data confidential after the validity period of this Agreement or after the termination of the Study.

拾貳、若甲方與受試驗者(包括其法定繼承人及其他法定請求權人)間，因為臨床試驗而發生紛爭或有發生紛爭之虞時，乙方應協助甲方解決。除因甲方之故意或過失所致者外，其相關處理費用及對第三人之賠償均由乙方負責。. In the event of a dispute or a possible dispute between Party A and a Study Subject (and their heirs and assigns) caused by the Study, Party B shall assist Party A in resolving the dispute. Party B shall pay for expenses and third-party compensation incurred in the dispute with the exception that the dispute was caused by Party A intentionally or by mistake.

拾叁、在臨床試驗之際，乙方須提供甲方藥品(或生技製品)之毒性、藥理作用等相關資料。甲方檢討資料後，尊重受試者之意願，並評估受試者之症狀及健康管理進行之。 Before the implementation of the Study, Party B shall provide Party A with the information about the toxicity and pharmacology of the Drug (or Product). Party A shall review the information provided by Party B, respect the Study Subject’s willingness in participating in the Study, and assess the symptoms and health management of the Study Subject before implementing the Study.

拾肆、臨床試驗期間，甲方發現受試驗者發生不良反應或有發生之虞，為充分保障受試驗者之權益，而無法繼續試驗時，應立即中止試驗並通知乙方，試驗委託者或其代理人若知悉試驗藥品發生非預期嚴重不良反應，應依法於期限內通報主管機關或其委託機構。乙方或其代理人於臨床試驗結束後(至少二年內)，若發現有非預期且直接影響受試者安全之資訊或重大事件，應自知悉日起十五日內，以書面通知計畫主持人、人體研究倫理審查委員會及受試者保護中心，由甲方評估是否通知受試者。.If Party A discovers any event or possible event of serious adverse reaction during the course of the Study, Party A shall stop the Study immediately and inform Party B of the event in order to protect the rights of the Study Subjects. If the Sponsor or its authorized representative is aware of any event of serious adverse reaction, the Sponsor shall notify the central competent authority or the contracted organization within the time limit in conformance with applicable laws and regulations.Within two years after the closure of the Study, the Party B or its authorized representative shall report in writing to the principal investigator, the IRB, and the HRPC upon discovery of information or a serious event that may unexpectedly and directly affect the safety of the subjects; the Party A conducting the Study shall evaluate whether subjects shall be notified of the information or event.

拾伍、試驗進行中雙方得隨時對試驗是否符合原計畫書內容進行稽核，他方應完全配合不得拒絕。.During the course of the Study, either Party may conduct an inspection or auditing any time to monitor if the Study has followed the Protocol; the other party shall cooperate with the inspection or auditing without any objection.

拾陸、乙方提供之藥品(或生技製品或醫療器材)若在其他醫院發現嚴重副作用時，應立即通知甲方。. If the Drug (Product or Device) provided by Party B has been discovered to cause a serious adverse event in another hospital, Party B shall inform Party A of the event immediately.

拾柒、雙方於實施試驗之際，應經衛生福利部核准，始得執行，且執行須遵守衛生福利部公告之「藥品優良臨床試驗準則」、中華民國相關法令及最新版赫爾辛基宣言。 Before the Study is implemented, it shall be approved by the Ministry of Healt and Welfare; both Parties shall abide by the Regulations for Good Clinical Practice announced by the Ministry of Health and Welfare, applicable laws of the Republic of China, and the latest version of the Declaration of Helsinki.

拾捌、甲方於試驗終了後，應儘速將經過及結果報告提供給乙方。When the Study is completed, Party A shall submit reports of the study process and results to Party B promptly.

拾玖、臨床試驗結果未取得雙方同意前不得告知第三人。但甲方係用在學術發表時，或依中華民國相關法規有向主管機關或人體研究倫理審查委員會通報義務者，乙方不得拒絕。 The results of the Study may not be released to the third party without permission from both Parties. However, if Party A releases the study results in an academic publication or if Party A is obliged to release the study results to the central competent authority or to the IRB in conformance with applicable laws and regulations, Party B may not object to the release.

貳拾、雙方之權利義務關係於本契約書中所未約定者，依中華民國相關法律之規定辦理。因本契約或臨床試驗所引起之爭議，雙方願依公平誠信原則先行協調解決，經協調不成，由臺灣臺中地方法院為第一審管轄法院。Other rights and obligations of both Parties not defined in this Agreement shall be determined in accordance with applicable laws of the Republic of China. In the event of a dispute caused by this Agreement or by the Study, both Parties shall attempt to resolve the dispute by negotiation following the principle of fairness and honesty; if negotiation fails, Taiwan Taichung District Court shall have jurisdiction over the dispute as the court of first instance.

貳壹、本契約之附件視同契約之一部分。任何於本契約簽訂前經雙方協議而未記載於本契約之事項，對雙方均無約束力。The Exhibit to this Agreement is deemed as part of the Agreement. Any other items discussed by both Parties prior to the signing of this Agreement but not recorded in this Agreement do not have binding power over either Party.

貳貳、本契約書壹式參份，甲乙雙方及試驗主持人各執乙份為憑。This Agreement will be executed in three counterpart copies, each of which shall be deemed an original; Party A, Party B, and the Principal Investigator shall each keep a counterpart copy of this Agreement.

立約人：

This Agreement is executed by the legal representatives of the Institution (Party A) and the Sponsor (Party B) as of the date written below:

甲方：臺中榮民總醫院 乙方：

Party A: Taichung Veterans General Hospital Party B:

法定代理人： 法定代理人：

Legal Representative: Legal Representative:

職稱： 職稱：

Title: Title:

科別：

Division

試驗主持人：

Principal Investigator:

中 華 民 國 年 月 日

(Year) (Month) (Day)