

1. 修訂並重申：於本院執行之臨床試驗案，合約內容需有下列條文。

第一條、 於奇美醫療財團法人奇美醫院(下稱甲方)執行之臨床試驗案，試驗委託者(下稱乙方)應遵守衛生署及健保局對臨床試驗使用健保費用之規定，若有違反致甲方受損害，乙方願負全部之賠償責任。

第二條、 甲方應依試驗計劃書之程序實施本試驗。如因此發生不良反應導致受試者受到傷害或死亡而需給予醫療照護或賠(補)償時，甲方及本院計畫主持人應協助乙方出面處理，但乙方應負擔因此而產生之醫療費用、賠(補)償費用及其他費用(包括但不限於訴訟費用及律師費用)。但若因甲方未依試驗計劃書之程序實施本試驗所致，不在此限。

第三條、 受試驗者之個人資料(包括一切可以直接或間接方式識別該受試驗者之資料)，甲、乙雙方不得無故洩漏。違反者就另一方或第三人造成之損害，應負全部之賠償責任(包括但不限於訴訟費及律師費)。

第四條、 乙方提供之各項研究費用(含主持人費)，皆須透明且經由甲方轉核發。

第五條、 本合約未盡訂明之事項，依中華民國之法令定之。

第六條、 若因本合約涉訟，雙方同意以臺灣臺南地方法院為第一審管轄法院。

第七條、 若中英文合約內容不同，則以中文版本為主。

第八條、 本合約一式參份，甲、乙雙方及計畫主持人各執壹份為憑。



1. Participant's medical costs and expenses incurred for the clinical trial conducted at Chi Mei Hospital (hereinafter referred to as "Party A") borne by the clinical trial sponsor (hereinafter referred to as "Party B") shall comply with the regulations set by the Department of Health and National Health Insurance Bureau, R.O.C. (Taiwan). If Party B's breach of the regulations causes any damage of Party A, Party B shall assume responsibility for all liabilities.
2. Party A shall conduct the clinical trials in accordance with procedures described in the Protocol. Party A and the investigator shall assist Party B in providing medical care or handling compensation claims for injuries and deaths resulting from adverse events. Payments of medical expenses, compensation and other expenses (including, but no limited to, litigation costs and attorney's fees) incurred are to be borne by Party B. This provision does not apply in situations where Party A does not conduct clinical trials in accordance with procedures described in the Protocol.
3. Both parties must not disclose the personal information of clinical trial participants (including identification data that can be linked to the participants directly or indirectly). The violator shall be subject to all liabilities and penalties caused to either party or the third party including, but not limited to, litigation costs and attorney's fees.
4. All research expenses (including investigator fees) paid by Party B shall be transparent; the payments shall be processed and transferred through Party A.
5. All other terms and conditions not stipulated in the Agreement shall be governed by and interpreted in accordance with Laws of the Republic of China.
6. In the event any lawsuits arising out of or relating to the Agreement, the parties agree that the Taiwan Tainan District Court shall be the competent court of jurisdiction in the first instance.
7. The Agreement is written in Chinese and English, and the parties agree that the Chinese version will prevail to the extent of any discrepancy in meaning between the Chinese version and its translation.

This Agreement is made in duplicate and each party shall hold one copy.

