

臺灣大學醫學院附設醫院 研究授權表(Delegation of Responsibilities Log)

說明：研究授權表依據藥品優良臨床試驗作業準則第 34 條（試驗主持人應保留其授權臨床試驗相關責任之試驗相關人員名單）及第 38 條（試驗主持人應確保所有試驗相關人員對試驗計畫書及研究藥品充分了解，以及其於臨床試驗中之責任與工作）制定，適用於所有參與研究執行之人員被授權執行之項目證明。

倫委會案號（REC Number）：_____

計畫名稱（Study Title）：_____

計畫主持人（Principal investigator）：_____

姓名 (Name)	計畫中角色 (Study Role)	被授權項目* (Study Tasks)	中文正楷簽名 (Signature)	開始日期 (Start Date)	計畫主持人簽名/日期 (PI Signature /Date)	結束日期 (End Date)	計畫主持人簽名/日期 (PI Signature /Date)

*被授權項目列於附件

***附件一 被授權項目 (Study Tasks)**

- | | |
|--|---|
| 1. Institutional Review Board/Research Ethics Committee communications & submissions | 13. (e)Case report form(CRF) entries, corrections and queries |
| 2. Screen/ recruit study participants | 14. Uses Interactive Web Response System(IWRS)/Interactive Voice Response System(IVRS) |
| 3. Explain/obtain informed consent form | 15. Randomise study participants(with or without IWRS/IVRS) |
| 4. Confirm eligibility(inclusion/exclusion) | 16. Investigational Product(IP) receipt, storage, temperature monitor prepares, dispenses, and/or administers IP |
| 5. Obtain medical/medication history | 17. Emergency unblinding |
| 6. Perform physical examination | 18. Administration of electronic patient-reported outcomes(ePRO) questionnaires, monitor compliance and patient training of ePRO completion |
| 7. Conduct study visit procedures (e.g. vital signs, height, weight, ECG) | 19. If other, please specify: |
| 8. Make study related medical decisions | (研究團隊可於第 19 項起自行增列) |
| 9. Evaluate study related test results | |
| 10. Assess Adverse Event(AE)/Serious Adverse Event(SAE) causality | |
| 11. Report Adverse Event(AE)/Serious Adverse Event(SAE) | |
| 12. Collect/process/ship biological samples | |