**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）：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| 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) |
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**\*被授權項目列於附件**

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| **\*附件一 被授權項目(Study Tasks)** | |
| 1. Institutional Review Board/Research Ethics Committee communications & submissions 2. Screen/ recruit study participants 3. Explain/obtain inform consent form 4. Confirm eligibility(inclusion/exclusion) 5. Obtain medical/medication history 6. Perform physical examination 7. Conduct study visit procedures (e.g. vital signs, height, weight, ECG) 8. Make study related medical decisions 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 | 1. (e)Case report form(CRF) entries, corrections and queries 2. Uses Interactive Web Response System(IWRS)/Interactive Voice Response System(IVRS) 3. Randomise study participants(with or without IWRS/IVRS) 4. Investigational Product(IP) receipt, storage, temperature monitor prepares, dispenses, and/or administers IP 5. Emergency unblinding 6. Administration of electronic patient-reported outcomes(ePRO) questionnaires, monitor compliance and patient training of ePRO completion 7. If other, please specify:   **(研究團隊可於第19項起自行增列)** |