

新光醫療財團法人新光吳火獅紀念醫院

臨床研究資料庫使用

臨床研究資料保密切結書

SHIN KONG WU HO SU MEMORIAL HOSPITAL Research Database Data
Confidentiality Agreement

立切結書人 _____（以下簡稱本人）於西元 ____ 年 ____ 月 ____ 日起，使用新光醫療財團法人新光吳火獅紀念醫院臨床研究資料庫（以下簡稱貴庫）資料，並切結遵守下列事項：

I, the undersigned _____ (hereinafter referred to as "I"), starting from ____ / ____ / ____ (yyyy/mm/dd), use the data of the SHIN KONG WU HO SU MEMORIAL HOSPITAL Clinical Research Database (hereinafter referred to as "the Database") and agree to the following:

一、保密義務：本人對於使用資料期間所知悉或持有之文件、電子檔案、釋出資料、圖表、分析報表、傳輸資料及相關作業機密，均應善盡保密義務；除專案必要分析使用外，不得洩露、告知、交付、複製、節錄或以其他方式移轉予第三人。即使離職、離院或終止合作，亦同。

I shall keep confidential all documents, electronic files, released data, charts, analytical reports, transmitted data and operational secrets obtained or possessed while using the data. Except for necessary project analysis, I shall not disclose, inform, deliver, copy, excerpt or transfer them to any third party, even after resignation or termination of cooperation.

二、禁止重識別及外部串接：本人不得對研究資料進行重識別化，包含與外部資料、公開資訊、院內其他資料或個人既有資訊比對、連結、推測或逆向還原，以辨識特定病人或受試者；未經貴庫或本院核准，不得與外部資料庫串接、比對或合併使用。

I shall not re-identify the research data, including by comparing, linking, inferring or reverse-engineering it with external data, public information, other hospital data or personal knowledge to identify specific patients or subjects. Without approval, I shall not link, compare or combine it with external databases.

三、IRB 核准範圍及期限：本人僅得於 IRB 核准之研究目的、資料範圍、資料期間、研究團隊成員及使用期限內使用研究資料；如 IRB 核准內容變更、期限屆滿、研究終止或本人不再屬核准研究團隊成員，應立即停止使用，並依本院規定辦理展延、歸還、刪除或銷毀。

I shall use the data only within the IRB-approved purpose, data scope, data period, research team and approved use period. If the IRB approval changes or expires, the study is terminated, or I am no longer an approved team member, I shall stop using the data and complete extension, return, deletion or destruction procedures under Hospital rules.

四、資訊系統與外部平台限制：本人不得將研究資料、個案層級資料、原始資料、資料處理或分析過程產生之相關檔案，或未經核准之統計結果，上傳、輸入或匯入至非本院核准之雲端硬碟、外部分析

注意：任何個人、組織或團體於使用、複製或散播本文件前，應確認其合法授權；未經新光吳火獅紀念醫院數位醫學部授權之使用、複製或散播，將依相關規定追究責任。

Note: Any use, copy or dissemination of this document requires legal authorization. Unauthorized use, copying or dissemination without prior authorization from SHIN KONG WU HO SU MEMORIAL HOSPITAL Department of Digital Medicine may be subject to relevant responsibility.

平台、生成式 AI 工具、私人設備、第三方系統或其他未授權資訊環境。

I shall not upload, enter, or import research data, case-level data, raw data, files generated during data processing or analysis, or unapproved statistical results to any cloud storage, external analysis platform, generative AI tool, personal device, third-party system, or other information environment not approved by the Hospital.

五、Data to go / Report to go 限制：若採 Data to go，本人應妥善保存、加密、使用及銷毀核准攜出資料，不得轉交、分享或提供予未經 IRB 及本院核准之第三人。若採 Report to go，本人不得以下載、匯出、複製、截圖、拍照、螢幕錄影、手抄、另存檔案或其他方式，將原始資料或個案層級資料攜出本院核准之安全環境。

For Data to go, I shall properly store, encrypt, use and destroy approved released data and shall not transfer, share or provide it to any third party not approved by the IRB and Hospital. For Report to go, I shall not download, export, copy, screenshot, photograph, screen-record, hand-copy, save or otherwise remove raw or case-level data from the Hospital-approved secure environment.

六、資料安全事件通報：如本人發現資料遺失、誤寄、誤傳、未授權存取、疑似外洩、系統異常或其他可能影響個人資料保護、資訊安全或受試者權益之情事，應立即通報 數位醫學部 及 IRB 計畫主持人；數位醫學部得依事件性質，通報資訊部、資通安全管理委員會及本院相關權責單位處理。

If I discover any data loss, misdelivery, mistransmission, unauthorized access, suspected data leakage, system abnormality, or any other event that may affect personal data protection, information security, or subject rights, I shall immediately notify the Department of Digital Medicine and the IRB Principal Investigator. The Department of Digital Medicine may, depending on the nature of the event, report the matter to the Information Technology Department, the Information Security Management Committee, and other relevant Hospital units for handling.

七、統計結果與成果發表：本人所產製之統計結果係依貴庫資料自行編製，公布發表之正確性由本人負責；內容僅限貴庫核可攜出之統計結果、彙整表格或圖表，未經核可不得發布，且不得含有可識別個人或具小樣本重識別風險之資訊，亦不得產製單筆資料之統計結果。

I am responsible for the correctness of statistical results produced from the Database. Publications or reports shall contain only approved statistical results, aggregated tables or charts, shall not include identifiable or small-sample re-identification risk information, and shall not produce results for single records.

八、違規處理：本人確認已閱讀「新光吳火獅紀念醫院臨床研究資料管理辦法」。如有侵犯個人隱私、違反受試者保護、個人資料保護、資訊安全、研究倫理或洩漏本院機密等情事，本人同意立即停止使用研究資料，並配合本院處置。經本院認定違規者，得限制本人及相關研究團隊 三年內不得申請、領取、使用或存取本院研究資料，並依相關規定懲處或追究法律責任。

I confirm that I have read the “Shin Kong Wu Ho-Su Memorial Hospital Clinical Research Data Management

注意：任何個人、組織或團體於使用、複製或散播本文件前，應確認其合法授權；未經新光吳火獅紀念醫院數位醫學部授權之使用、複製或散播，將依相關規定追究責任。

Note: Any use, copy or dissemination of this document requires legal authorization. Unauthorized use, copying or dissemination without prior authorization from SHIN KONG WU HO SU MEMORIAL HOSPITAL Department of Digital Medicine may be subject to relevant responsibility.

Regulations.” If I violate privacy, subject protection, personal data protection, information security, research ethics, or disclose Hospital confidential information, I agree to immediately stop using the research data and comply with the Hospital’s actions. If confirmed as a violation, I and the relevant research team may be restricted from applying for, receiving, using, or accessing Hospital research data for three years, and may be subject to disciplinary or legal action.

九、中英文效力：本人瞭解並同意本切結書有中文與英文對照版本；如解釋有歧異時，以中文版本為準。本切結書正本由貴庫收執，影本由立切結書人收執。

I understand and agree that this agreement has Chinese and English versions. In case of discrepancies, the Chinese version shall prevail. The original is held by the Database, and a copy is kept by the undersigned.

此 致 To

新光吳火獅紀念醫院研究資料庫

SHIN KONG WU HO SU MEMORIAL HOSPITAL Research Database

立切結書人 Undersigned：

(簽章 Signature)

身分證統一編號 ID Number：

地址 Address：

聯絡電話 Phone Number：

服務單位 Institution：

中 華 民 國

年

月

日

注意：任何個人、組織或團體於使用、複製或散播本文件前，應確認其合法授權；未經新光吳火獅紀念醫院數位醫學部授權之使用、複製或散播，將依相關規定追究責任。

Note: Any use, copy or dissemination of this document requires legal authorization. Unauthorized use, copying or dissemination without prior authorization from SHIN KONG WU HO SU MEMORIAL HOSPITAL Department of Digital Medicine may be subject to relevant responsibility.