

衛生福利部桃園醫院人體研究倫理審查委員會

Medical Ethics and Institutional Review Board of Taoyuan General Hospital, Ministry of Health and Welfare

同意人體研究/人體試驗證明書

Certificate of Approval

核發日期：2024年6月11日

計畫名稱：桃園航空城跨世代研究—社會變遷對不同世代居民身心健康探討

計畫主持人：詹金淦、陳保中

共/協同主持人：劉介修、李俊賢

執行機構名稱：衛生福利部桃園醫院

計畫版本/日期：V4/2024.06.04

受試者同意書版本/日期：V4/2024.06.04

受試者同意書(兒童版)版本/日期：V3/2024.04.26

問卷(國小學童)版本/日期：V2/2024.04.30

問卷(國小家長)版本/日期：V2/2024.04.30

問卷(國小祖父母)版本/日期：V2/2024.04.30

問卷(國中學童)版本/日期：V2/2024.04.30

問卷(國中家長)版本/日期：V2/2024.04.30

問卷(國中祖父母)版本/日期：V2/2024.04.30

IRB 編號：TYGH113014

研究執行期間：2024年6月11日至2026年12月31日

本次核准期間：2024年6月11日至2025年6月10日

依據本委員會標準作業程序、並符合藥品優良臨床試驗準則及政府相關法律規章，本計畫案經本院人體研究倫理審查委員會審查通過，期間應接受本委員會之監督，特此證明。

主任委員：張懷陸

Protocol Title : Taoyuan Aviation City Cross-Generation Study—exploring the impact of social changes on the physical and mental health of residents of different generations

Principle Investigator : Chin-Kan Chan, Pau-Chung-Chen

Co/Sub-Investigator : Chieh-hsiu Liu, Jyuhn-Hsiarn Lee

Implementing Institution : Ministry of Health and Welfare Taoyuan General Hospital

Protocol Version/Date : V4/2024.06.04

Informed Consent Form Version/Date : V4/2024.06.04

Informed Consent Form Child Version/Date : V3/2024.04.26

Questionnaire(Elementary School Student) Version/Date: V2/2024.04.30

Questionnaire(Elementary School Parent) Version/Date: V2/2024.04.30

Questionnaire(Elementary School Grandparents) Version/Date: V2/2024.04.30

Questionnaire(Junior High School Student) Version/Date: V2/2024.04.30

Questionnaire(Junior High School Parent) Version/Date: V2/2024.04.30

Questionnaire(Junior High School Grandparents) Version/Date: V2/2024.04.30

IRB No : TYGH113014

Period of Project: 2024/6/11-2026/12/31

Period of Approval: 2024/6/11-2025/6/10

According to the written operating procedure and complies with GCP, and the applicable regulatory requirements, this study project is approved by the Medical Ethics and Institutional Review Board of the Taoyuan General Hospital, Ministry of Health and Welfare.

Chairman : Hwai-Luh, Cheng

衛生福利部桃園醫院人體研究倫理審查委員會

Medical Ethics and Institutional Review Board of Taoyuan General Hospital, Ministry of Health and Welfare

- 一般審查 Full-Committee Review
- 簡易審查 Expedited Review*
- 期中持續審查 Interim Review
- 變更審查 Amendment Review

該計畫後續定期追蹤之程序及要求：

1. 凡需送衛生福利部審核之計畫案件，須取得衛生福利部審核同意函後方可開始執行。
2. 期中報告追蹤頻率：每 6 個月
※下次持續審查報告繳交截止日期：2024/12/10，應於到期日至少 6 週前提出持續審查申請，本案需經持續審查，方可繼續執行，若於到期日前完成研究，請繳交結案報告。
3. 結案報告：已完成之研究應於研究執行期間結束後三個月內繳交結案報告，除維護受試者安全之必要作為外，於核准期間結束後應停止執行所有受試者相關之研究程序。
4. 若需展延，計畫主持人須於到期至少 6 週前提出展延計畫之申請，經本委員會通過後，方可繼續執行。
5. 研究計畫內容有任何變更或修正(含研究執行期間變更)，須於研究執行期間內向本會提出申請，本會不受理未在研究執行期間內提出之變更或修正案。變更或修正未獲本會核准前，須依原核准範圍執行。

Regular follow-up of procedures and requirements :

1. If indicated by the regulations and laws, this project should be taken after the approval of Ministry of Health and Welfare, R.O.C.
2. Submission of mid-term report : Every 6 months
※Next Deadline of Continuing Report : 2024/12/10. If the study is completed prior to the approved expiration date, provide the Final Report.
3. Final report : Regarding completed project, the closure reports shall be submitted within three months of its approved expiry date. Except for the health of the participants, all the procedures of the project shall be terminated on its approved stated deadline.
4. The principle investigator is required to submit the application for extension at least 6 weeks before the expired date.
5. Any changes or amendments to the project (including the project period), please submit an amendment application to TYGH IRB within its approved period. Any changes or amendments in any other way will not be accepted. Before the approval of the amendment application, the project is carried out according to its previously approved plan.

※已通過審查的所有計畫案件均應獲得最終核准，本會有權撤銷有疑義的計畫許可書。

※All protocols that have been passed the review should be subject to final endorsement, the Board has the right to revoke the approval of doubtful.