



臺北榮民總醫院
TAIPEI VETERANS GENERAL HOSPITAL

201 SHIH-PAI ROAD, SEC. 2
TAIPEI, TAIWAN 11217
REPUBLIC OF CHINA
TEL: (886)-2-2871-2121

同意臨床試驗 / 研究證明書

IRB 編號：2017-01-023C

計畫編號：

計畫名稱：以次世代定序篩檢家族型與早發型失智症之遺傳病因

部門/計畫主持人：精神部/ 洪成志醫師

共同主持人：蔡佳芬醫師、傅中玲醫師、花蓮慈濟醫院蔡欣記醫師、國立陽明大學董建億助理研究員

計畫文件版本日期：

1. 計畫書：Ver 1.0 2016-12-27
2. 中文摘要：Ver 1.5 2016-12-28
3. 受試者同意書：Ver 1.5 2017-02-17
4. 資料及安全性計畫：Ver 1.0 2016-12-27

依據本委員會標準作業程序、及政府相關法律規章，本計畫案經本院人體試驗委員會(三)106年02月22日第41次會議審查通過，有效期限為一年，至107年02月21日止，特此證明。

本委員會的運作符合藥品優良臨床試驗準則及政府相關法律規章。

計畫主持人須依國內相關法令及本院規定通報嚴重不良反應事件及非預期問題。

計畫主持人須於到期前2個月至6週（至少前6週）提出持續審查之申請，本案須經本院人體試驗委員會通過後，方可繼續執行。（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）



陳適安

臺北榮民總醫院
人體試驗委員會
主任委員
陳適安

中 華 民 國 1 0 6 年 0 3 月 0 6 日



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Clinical Trial/Research Approval Letter

Mar. 06, 2017

IRB-TPEVGH No.: 2017-01-023C

Protocol No:

Protocol Title: Screening genetic causes of familial dementia and early-onset dementia by next generation sequencing

Department/Principal Investigator: Department of Psychiatry / Chen-Jee Hong, M.D.

Co-Investigator: Chia-Fen Tsai, M.D., Jong-Ling Fuh, M.D., Hualien Tzu Chi Hospital/
Hsin-Chi Tsai, M.D., National Yang-Ming University, Chien-Yi Tung

Version date of documents:

1. Protocol : Ver 1.0 2016-12-27
2. Chinese Synopsis: Ver 1.5 2016-12-28
3. Informed Consent Form: Ver 1.5 2017-02-17
4. DSMP: Ver 1.0 2016-12-27

According to the written operating procedures, GCP, and the applicable regulatory requirements, this study project is approved by the 41st meeting of the Institutional Review Board (3) of Taipei Veterans General Hospital on Feb 22, 2017. This approval is valid for 1 year till Feb 21, 2018.

The board is organized under, and operates according to International Conference on Harmonisation (ICH) / WHO Good Clinical Practice (GCP) and the applicable laws and regulations.

The principal investigator is required to report Serious Adverse Events and Unanticipated Problems in accordance with the governmental laws and regulations and TPEVGH requirements.

The principal investigator is required to submit the application for extension at least 6 weeks before the expiration date. (If indicated by the regulations and laws, this project should be taken after the approval of Ministry of Health and Welfare, R.O.C.)



Shih-Ann Chen, M.D.
Chairman
Institutional Review Board
Taipei Veterans General Hospital
Taiwan, R.O.C.



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同意執行證明書

日期：106 年 02 月 22 日

IRB 編號：2017-01-023C

計畫編號：

部門/計畫主持人：精神部/ 洪成志醫師

計畫名稱：以次世代定序篩檢家族型與早發型失智症之遺傳病因

本案經本院人體試驗委員會（三）審查通過，並確認由本院人體試驗委員會（三）自行列管，正式同意本案執行。

陳適安

臺北榮民總醫院
人體試驗委員會
主任委員
陳適安

Implementation Letter

Date: Feb 22 , 2017

TPEVGH IRB No.: 2017-01-023C

Protocol No.:

Department/Principal Investigator: Department of Psychiatry/ Chen-Jee Hong, M.D.

Protocol Title: Screening genetic causes of familial dementia and early-onset dementia by next generation sequencing

The protocol has been approved by the Institutional Review Board (3) of Taipei Veterans General Hospital and supervised by the Institutional Review Board (3) of Taipei Veterans General Hospital.

The implementation of the protocol is approved.

Shih-Ann Chen

Shih-Ann Chen , M.D.
Chairman
Institutional Review Board
Taipei Veterans General Hospital
Taiwan, R.O.C.

