



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：2018-02-008BC

計畫名稱：運用人類臍帶瓦頓式凝膠間葉幹細胞治療糖尿病動物之研究

部門/計畫主持人：重症醫學部 / 蔡佩君醫師

共同主持人：陳天華醫師、葉長青醫師、黃本湘醫師

計畫文件版本日期：

1. 計畫書：V1 20180102
2. 中文摘要：V2 20180215
3. 受試者同意書：V2 20180215
4. 資料及安全性計畫：waived
5. 個案報告表：Version1 20180102

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(二)於107年02月27日審查通過，有效期限為一年，至108年02月26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 7 年 0 2 月 2 7 日



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## Clinical Trial/Research Approval Letter

Feb. 27, 2018

IRB-TPEVGH No.: 2018-02-008BC

Protocol Title: Study the therapeutic effect effects of human Wharton's jelly mesenchymal stem cells (WJ-MSCs) on diabetic animals

Department/Principal Investigator: Department of Critical Care Medicine / Pei-Jiun Tsai, M.D.

Co-Investigator: Tien-Hua Chen, M.D., Chang-Ching Yeh, M.D., Ben-Shian Huang, M.D.

Version date of documents:

1. Protocol : V1 20180102
2. Chinese Synopsis: V2 20180215
3. Informed Consent Form: V2 20180215
4. DSMP: waived
5. Case Report Form: Version1 20180102

According to the written operating procedures, GCP, and the applicable regulatory requirements, this study project is approved by the Institutional Review Board (2) of Taipei Veterans General Hospital on Feb 27, 2018. This approval is valid for 1 year till Feb 26, 2019.

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*

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：107年3月12日

IRB 編號：2018-02-008BC

部門/計畫主持人：重症醫學部/蔡佩君醫師

計畫名稱：運用人類臍帶瓦頓式凝膠間葉幹細胞治療糖尿病動物之研究

本案經本院人體試驗委員會（二）審查通過，由本院人體試驗委員會（二）自行列管，由臨床研究受試者保護中心複核相關文件，代表機構正式同意本案執行。



臺北榮民總醫院  
臨床研究受試者保護中心主任  
黃信彰副院長

黃信彰

Implementation Letter

Date: Mar 12, 2018

TPEVGH IRB No.: 2018-02-008BC

Department/Principal Investigator: Department of Critical Care Medicine /  
Pei-Jiun Tsai, M.D.

Protocol Title: Study the therapeutic effect effects of human Wharton's jelly  
mesenchymal stem cells (WJ-MSCs) on diabetic animals.

The protocol has been approved by the Institutional Review Board (2) of Taipei Veterans General Hospital and supervised by 「the Institutional Review Board (2) of Taipei Veterans General Hospital」. After the review by Human Research Protection Center, the implementation of the protocol is approved.



Shinn-Jang Hwang

Vice Superintendent Shinn-Jang Hwang, M.D.  
Director of Human Research Protection Center  
Taipei Veterans General Hospital, Taiwan, R.O.C.