

國立臺灣大學醫學院附設醫院A/B/C/D研究倫理委員會

Research Ethics Committee A/B/C/D

National Taiwan University Hospital

7, Chung-Shan South Road, Taipei, Taiwan 100, R.O.C

Phone: (02)2312-3456 Fax: (02)23951950

臨床試驗/研究許可書

許可日期：0000 年 00 月 00 日

倫委會案號：

計畫編號：

計畫名稱：

試驗機構：

部門/計畫主持人：

上述計畫業經 0000 年 00 月 00 日本院 A/B/C/D 研究倫理委員會第 00 次會議審查同意，符合研究倫理規範(，並同意免除受試者知情同意)。本委員會的運作符合優良臨床試驗準則及政府相關法律規章。

本案需經衛生福利部核准同意後，該計畫始得進行試驗。

本臨床試驗/研究許可書之有效期限為 1 年(自 2017 年 00 月 00 日至 2018 年 00 月 00 日止)，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，並應於到期日至少 6 週前提出持續審查申請表，本案需經持續審查，方可繼續執行。

主任委員

Clinical Trial/Research Approval

Date of approval: 000 00, 0000

NTUH-REC No. :

Protocol No.:

Title of protocol :

Trial/Research Institution :

Department/ Principal Investigator : Department of / Dr.

The protocol (and the request for the waiver of informed consent have) has been approved by the 45th meeting of Research Ethics Committee A/B/C/D of the National Taiwan University Hospital on Sep 6, 2013. The committee is organized under, and operates in accordance with, the Good Clinical Practice guidelines and governmental laws and regulations.

Approval by the Ministry of Health and Welfare is mandatory before project implementation.

The duration of this approval is one year (from Sep 27, 2013 to Sep 26, 2014). The investigator is required to report Serious Adverse Events and Unanticipated Problems in accordance with the governmental laws and regulations and NTUH requirements and apply for a continuing review not less than six weeks prior to the approval expiration date.

Daniel Fu-Chang Tsai, M.D.

Chairman

Research Ethics Committee A/B/C/D

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計畫文件版本日期 **Version date of documents :**

- (1) 計畫書 *Protocol:*
- (2) 中文摘要 *Chinese Synopsis:*
- (3) 同意書 *ICF:*
- (4) 個案報告表 *CRF:*
- (5) 主持人手冊 *IB:*
- (6) 問卷 *Questionnaire:*
- (7) 其他文件 *Other documents:*

<圓戳章>