

國立臺灣大學醫學院附設醫院C研究倫理委員會

Research Ethics Committee C

National Taiwan University Hospital

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臨床試驗/研究許可書

許可日期：2020年3月18日

倫委會案號：202001014DSC

計畫名稱：探討放化療治療引起口腔潰瘍的癌症病人使用口適怡 Oral Gel(NaSIL)液體口腔凝膠對改善口腔潰瘍狀況與口腔相關品質生活之成效。

試驗機構：國立臺灣大學醫學院附設醫院

部門/計畫主持人：牙科部 陳敏慧醫師

上述計畫業經2020年3月16日本院C研究倫理委員會第127次會議審查同意，符合研究倫理規範。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。

本臨床試驗/研究許可書之有效期限為1年(自2020年3月18日至2021年3月17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

蔡甫昌

Clinical Trial/Research Approval

Date of approval: Mar 18, 2020

NTUH-REC No. : 202001014DSC

Title of protocol : Explore the efficacy of Oral Gel (NaSIL) on the improvement of Radiotherapy/Chemotherapy-induced Oral Mucositis' condition and patients' Oral Health-Related Quality of Life.

Trial/Research Institution : National Taiwan University Hospital

Department/ Principal Investigator : Department of Dentistry/ Dr. Min Huey-Chen

The protocol has been approved by the 127th meeting of Research Ethics Committee C of the National Taiwan University Hospital on Mar 16, 2020. The committee is organized under, and operates in accordance with, the Good Clinical Practice guidelines and governmental laws and regulations.

The duration of this approval is one year (from Mar 18, 2020 to Mar 17, 2021). 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 C

Daniel Fu-Chang Tsai