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國防醫學院三軍總醫院

人體試驗審議會

人體試驗計畫同意函

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本審議會核准編號：2-108-05-127

計畫名稱：同時脾臟切除手術對於肝癌病患接受肝臟移植手術的腫瘤預後分析比較研究

執行機構：三軍總醫院

計畫主持人：一般外科樊修龍醫師

計畫書版本日期：Version 2.0:2020.03.20

本會審核通過之其他文件版本及日期：

中文摘要：Version 2.0:2020.03.20、個案報告表：Version 2.0:2020.03.20

業經本院 2020 年 3 月 30 日人體試驗審議會第一組審查通過免簽署受試者同意書，該計畫案經評估屬低度風險，(持續審查頻率為每年一次)，有效期限至 2021 年 3 月 29 日，特此證明。

本審議會的運作，遵循藥品優良臨床試驗準則及政府相關法律規章。計畫主持人應於同意函有效期屆滿前二個月，提出展延申請，本案須經本院人體試驗審議會通過後，方可繼續執行。

Letter of Approval

Institutional Review Board, Tri-Service General Hospital

TSGHIRB No.: 2-108-05-127

Protocol title : Comparison between the outcomes of hepatocellular carcinoma in patients underwent liver transplantation with and without synchronic splenectomy

Research institution : Tri-Service General Hospital

Principle investigator : Hsiu-Lung Fan

Protocol version : Version 2.0:2020.03.20

Other documents :

Chinese Abstract : version 2.0:2020.03.20、CRF : Version 2.0:2020.03.20

On 03/30/2020, the Institutional Review Board A of the Tri-Service General Hospital approved the above-named application signature exemption on ICF. Assessed as Low Risk, the protocol is subject to follow-up review annually. The Board is organized and operated in compliance with International Conference on Harmonization (ICH) / WHO Good Clinical Practice (GCP) and applicable laws and regulations. This approval is valid for 1 year till 03/29/2021. The principle investigator is required to submit the application for extension 2 months before the expiration date.



Institutional Review Board

余慕賢 Yu Ma Hsien

Chairman_____.

The Committee is Organized and operates in accordance with ICH6 GCP regulations and guideline.
本審議會組織與運作皆遵守 ICH6 GCP 規定