彰化基督教醫院
CHANGHUA CHRISTIAN HOSPITAL

同意臨床試驗證明書
Clinical Trials Approval Certificate(New Protocol)

[redacted]

計畫中文名稱： 彰化基督教醫院胃黏膜下腫瘤的患者行微創手術治療方法的比較
計畫主持人： 林國華 / 協同主持人：張維容
試驗機構名稱： 彰化基督教醫療財團法人彰化基督教醫院
本會編號：220117
核准日(審查通過日)： 西元 2022 年 01 月 20 日
核准臨床試驗期間： 西元 2022 年 01 月 20 日 至 西元 2023 年 01 月 19 日止

計畫書： 版本 1，2022-01-05
病歷回溯資料收集表： 版本 1，2022-01-05
免除受試者同意書

未預期事件或藥品嚴重不良反應通報、後續定期追蹤之程序及應注意事項，請參閱背面。

Protocol Title: Different Approach of Minimal Invasive Surgery for Gastric Subepithelial Tumor from A Single-Center Experience
Principal Investigator(s): Lin kuo hua / Co Investigator：Chang Wei-Jung
Institution: CHANGHUA CHRISTIAN HOSPITAL
CCH IRB No. : 220117
Date of Approval: Jan 20, 2022
Duration of Approval: from Jan 20, 2022 to Jan 19, 2023

Protocol: Version 1, Jan 05, 2022
Retrospective data collect form: Version 1, Jan 05, 2022
Waiver of documentation of informed consent

See the back of this page for the procedures for reporting unanticipated problems, or drug serious adverse reactions, or interim, and other important notes.

彰化基督教醫院
第三人體試驗委員會
主任委員： 顏旭亨

Sincerely Yours
HsuHeng Yen, M.D.
Chairman
Institutional Review Board Committee C
Changhua Christian Hospital, Taiwan

彰化基督教醫院 人體試驗委員會 Institutional Review Board Changhua Christian Hospital

[redacted]
(signature, date)

本會組織與執行皆符合 ICH-GCP
The Institutional Review Board performs its functions according to written Operating procedures and complies with ICH-GCP and with the applicable regulations.

彰化基督教醫院
CHANGHUA CHRISTIAN HOSPITAL

未預期事件通報、後續定期追蹤之程序及應注意事項：

1. 院內受試者發生死亡或危及生命案例應該在獲知日起七天以內通報本委員會，其他非預期嚴重藥品不良反應應於十五天以內向本委員會通報。
2. 可能危害受試者安全、影響試驗執行之新發現或影響人體試驗委員會同意試驗繼續進行之新發現，須向本委員會報告。
3. 期中報告：**應於　西元 2022 年 11 月 19 日 前繳交期中報告。**
   核准有效期限屆滿，若尚未通過期中報告追蹤審查，不得繼續試驗。(計畫主持人，未依規定繳交期中報告，本會針對該研究案，於應繳交日起暫停納入新受試者，且本會得拒絕計畫主持人申請新案，並直到該期中報告繳交。)。
4. 結案報告：試驗完成後，應將執行情形及結果以書面報告本會核備。
5. 暫停或終止計畫報告：計畫完成前就暫停或停止收案與追蹤，應與書面「計畫暫停或終止摘要表」，送交本會核備。
6. 嚴重或持續不配合本委員會規範，未能遵循以上事項，可能導致您的研究計畫暫停或永久終止，並影響您未來送審計畫的權益。
7. 為了受試者安全，計畫主持人必須遵循以上之規範，以確保能繼續執行試驗。

Procedures for reporting Unanticipated Problems, or interim, and other important notes:

1. If subject(s) die(s) or hospitalized, IRB should be notified within 7 days of becoming aware of this. For other unexpected serious adverse drug reactions, IRB should be notified within 15 days.
2. If any new findings affect the safety of the participants or others, or the implementation of the study, or decision of IRB as to allowed to continuing of the study, IRB should be informed promptly.
3. Interim report: **An interim report should be submitted by Nov 19, 2022.**
   If the interim report has not been submitted by the deadline, the study must be halted. (If a principal investigator fails to submit an interim report on schedule, IRB may suspend review of other protocols submitted by the investigator, and may refuse to review any further applications made by the investigator.)
4. Final report: When the study has been completed, details of the study implementation and of the results obtained should be submitted to IRB in writing for review.
5. For any reason, the study is terminated prior to the completion of a study, the summary report should be submitted to IRB.
6. Serious or repeated failure to comply with regulations and with the above requirements may result in the study being suspended or terminated, and may affect you to submit studies for review in the future.
7. Principal investigators must follow in order to continue study procedures for the safety of the subjects.

彰化基督教醫院 人體試驗委員會 Institutional Review Board Changhua Christian Hospital