中山醫學大學附設醫院人體試驗委員會

Institutional Review Board
Chung Shan Medical University Hospital
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臨床試驗計畫許可書

CSMUH No: CS13007

計畫名稱：運用健保資料庫探討肝硬化患者罹患冠狀動脈疾病的風險
計畫主持人：林俊哲
版　　本：【計畫書：version：1.0；date：10-Jan-2013】
許可書有效期：　103 年　1 月 23 日
期中報告繳交頻率：每十二個月繳交一次，若需申請延長試驗，請於效期屆滿前申請。

上述計畫依據本院人體試驗委員會簡易審查作業基準，經審查通過同意執行。有關計畫主持人的職責、義務、及注意事項均詳列於背面，請參閱並遵守。

主任委員　韓志平

中　華　民　國　一　〇　二　年　一　月　二　十　九　日

Permission of Clinical Trial
Chung Shan Medical University Hospital

Date: January 29, 2013

Protocol Title: Liver cirrhosis and the risk of coronary artery disease: population-based study
Principle Investigator: LIN, CHUN-CHE
Version: see above
Frequency of Interim Report: every 12 months. Please file an extension before the expiry date, if you need.
The above research protocol fit in with the expedited review cases. It has already been approved on January 24, 2013 and valid through January 23, 2014. About the essential duties, obligations and responsibilities of the principal investigator (PI), please refer to the back page.

Chih-Ping Han

Chih-Ping Han, MD/PhD.
Chairman
Institutional Review Board

本委員會組織與執行皆符合 ICH-GCP 規範及赫爾辛基宣言之精神
This Committee has been organized and operated in conformance with ICH-GCP requirements and the essence of Declaration of Helsinki.

計劃主持人注意事項（PI Duties, Obligations and Responsibilities）

依據衛生署法規與本院 IRB 規範，計畫主持人有義務依照計畫書執行研究，確保受試者權益，並且審慎控管本研究中各種介入方式的品質。提醒您，必須切實遵守以下事項：

1. 保護受試者的權益（包括人身的隱私與其資料的隱密）、安全、與最大利益。
2. 主動將受試者同意書影本送交簽署人自行留存保管，是善意負責任的表現。依據本委員會核准之計畫書版本執行研究，受試者同意書、計畫書與原始核准文件，非經申請變更核准，不得擅自改變。
3. 誠實揭露您經費來源，負責監督團隊成員，都確實遵守優良臨床試驗規範(GCP) 、人體研究法及及相關法規。
4. 需按照本委員會規定時限繳交期中（3、6、9、12 個月中繳交一次）及結案（結案後三個月內）報告。一年內結案之研究計畫，免繳期中報告，僅需繳交結案報告即可；但衛生署列管案件應依其規定時限繳交。其它特殊案件，得由本委員會在同意函上載明個別規範與管理。未按時繳交期中及期末報告且已逾期三個月以上者，本委員會將拒絕該主持人申請新案，並暫停其審理中之案件，直到該主持人完成補繳程序，始重新開放。許可函有效期為一年或多年，若需申請延長試驗，需於效期屆滿前，繳交期中報告及延長試驗申請書（最好在效期屆滿前 2 個月內）。
5. 配合並接受本委員會實地訪視與查核監督，受試者招募資料須事先送審，修正計劃未經提案核准，不得施行。
6. 取得同意書過程中，須給受試者足夠考慮時間並充分告知詳情，再取得有效同意。查驗登記案件需繳交受試者知情同意回饋評估表單，其它有弱勢族群（易受傷害受試族群）參與之試驗，按本委員會決議辦理。
7. 遵守衛生署 950818 研究用人體檢體採集與使用注意事項規範、981214 人體試驗管理辦法及 990203 人體生物資料庫管理條例規範，採取檢體需先經受試者（捐贈者）允許，簽署同意書，採取檢體，作為研究樣本。
8. 衛生署列管之人體試驗需設定電腦警示視窗（可洽臨床試驗中心），並主動告知病歷室永久保存病歷。如屬「醫療法」所規範之人體試驗，廠商及主持人須據實申報並同時取得衛生署及本委員會之核准函後，始得開始執行試驗，修正案亦同。
9. 發生嚴重未預知（指未預期或超過預期）事件，或重大新發現，足以造成受試者或他人發生風險危害，需緊急先行處置，因而背離或改變原先核准之研究計劃書，事後應儘快向本委員會報告。
10. 藥物試驗受試者發生任何嚴重不良事件，主持人應立即通知試驗委託者，並儘快提供書面報告。發生未預期之嚴重藥品不良反應，試驗主持人應立即通知人體試驗委員會；但若試驗計畫書或其他文件明確排除者，不在此限。其餘非藥物試驗，發生(1)足以影響研究對象權益、安全、福祉之情事，(2)嚴重不良事件或反應，或(3)影響計畫風險利益評估之重要事件或資訊，主持人應立即通知人體試驗委員會。
11. 嚴重或持續不配合本委員會規範、未能遵循以上十點事項，可能導致您的研究計畫暫時中止或永久終止，並影響您未來送審計劃的權益。

According to the DOH Regulations and CSMU Hospital IRB codes, you, as Principal Investigator are responsible for ensuring that the research study is conducted according to the protocol, assuring that human subjects are protected and controlling any intervention being used during the study. You should comply with the following:

1. Protect the privacy, confidentiality, rights, safety, and welfare of the research subjects.
2. A copy form of signing ICF shall be given to the participants for keeping. Conduct the study in compliance with the IRB approved study protocol. Maintain IRB correspondence in the appropriate study file. Each change in the Consent, Protocol Document and Authorization Form must be reviewed and approved prior to use.
3. Disclosing relevant financial information, and directly oversee your study personnel to assure that they are performing their duties according to GCP, human research law and related regulation.
4. As required by IRB, provide a Progressing Report within3、6、9、12 months after the start of the trial and a Final Report within 3 months after the conclusion of the study. Progressing report is not applicable for studies concluded within 12 months, except for DOH-controlled studies. For other special studies, individualized requirements will be stated on the approval letter. For investigators who do not submit progressing report or final report on required schedule or behind for over 3 months, any his/her new application will be declined and application under reviewing process will be suspended until the required reports have been submitted. This approval is validated for one or more than one year. For the extension of this approval, interim report and the application form for approval extension should be submitted before the expiration (2 months before the expiry date will be preferred).
5. Be willing to coordinate to accept the IRB site visit and surveillance. Submit all advertisements and other recruitment material for IRB approval prior to use. All amendments have to be submitted to the IRB for approval before they can be implemented.
6. Allow adequate time and discussion to take place during this Informed Consent process to assure that the potential subjects can make an informed decision of whether to participate. Assess whether the subject comprehends the content of the ICF document. Subjects' ICF Feedback tools are required for all registration trials and certain research trials involving vulnerable participants, based on the IRB's decision.
7. Following the Guidelines for collection and use of human specimens for research (950818), Regulations for Human trials (981214), Regulations for the Administration of Human Biobank (990203), PI have to obtain the agreement from the subjects (donors) by signing the informed consent, before taking the research sample.
8. For DOH regulated new drugs, new medical instruments and techniques related clinical trials, computer warning system (alarm windows) is required and subject's medical histories should be preserved permanently. In addition to IRB agreement, the PI (& sponsor) must receive the DOH approval before starting those medical law restricted human trials.
9. Promptly report changes to the research activity, owing to unanticipated problems involving risk / benefit to human subjects, etc.
10. In drug and medical device related human research, PI should alert the sponsor of any SAE soon and advise the IRB of every SUSAR from the research subjects immediately, except for the ruling out form protocols or special documents. In non-drug and non-medical related human research, PI needs to report to IRB soon, in case of any (1)SAE/SUSAR, (2)damage to the subjects' rights/interests/privacy/confidentiality/welfares, (3)signals or information that changes to the risk/benefit ratio.
11. Serious or continuing noncompliance with the IRB requirements & Failure to follow the above 10 rules could result in suspension or termination of your research protocol.