动物实验福利伦理审查决议

Approval Letter of Laboratory Animal Welfare and Ethical

项目名称 Study Title	基于AMPK和RhoA/ROCK通路探讨恩格列净对2型糖尿病心肌保护的机制研究		
项目来源 Issued BY	河北省科技计划项目		
主要研究者 Principal investigator	周红	科室 Department	内分泌科
送审日期 Date Submitted	2022/03/05	审查决议编号 Approval Letter No.	2022-AE136
品种/品系 breed/strain	db/db小鼠		
动物级别 Grade	SPF	数量（只） Number (♀; ♂)	雌（♀）_____; 雄（♂）30只;
计划执行时间 Period of Protocol	2022/05至2023/05		
审查意见和结论 Review opinions and conclusions	根据该研究的实验设计，经伦理委员会审查，符合动物保护、动物福利和伦理原则，符合国家实验动物福利伦理的相关规定。 According to the experimental design of the study, after the review of the ethics committee, that it was in line with the principles of animal protection, animal welfare and ethics, and the relevant provisions of the national experimental animal welfare ethics. 主审委员（签字）[redacted] 主任委员（签字）[redacted] 日期：2022 年 3 月 7 日		

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河北医科大学第二医院科研伦理委员会
Research Ethics Committee of the second hospital of Hebei Medical University

本伦理委员会组成及操作符合药物临床试验质量管理规范和伦理委员会药物临床试验伦理审查工作指导原则及相关法律法规。

The composition and operation of the Ethics Committee conform to the Criterions for the Quality Control of Clinical Trial of Drugs, the guiding principles for ethical review of drug clinical trials and related laws and regulations.

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。发生严重不良事件，及时提交严重不良事件报告。发生违反试验方案情况须及时报告本伦理委员会。

In order to protect the health and rights of the subjects, the applicant should follow the GCP principles and programs approved by the Ethical Committee during the clinical studies. If any changes are made to the primary investigator(s), the clinical research protocol, informed consent, recruitment materials, etc., the applicant is requested to submit an amendment for review. In the event of a serious adverse event, a serious adverse event report should be submitted in time. The violation of the protocol shall be promptly reported to the Ethics Committee.

请按照伦理委员会规定的年度/定期跟踪审查频率，在截止日期前 1 个月提交研究进展报告；申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。完成临床研究，请申请人提交结题报告。

The applicant should submit the study progress report one month before the deadline according to the frequency of the annual / periodic follow-up examination. If the applicant suspends or prematurely terminates the clinical research, the suspension / termination report should be submitted in time. The applicant should submit the final report when they complete the clinical study.

本试验年度/定期跟踪审查频率为一年，本批件有效期为一年。

The annual / periodic follow-up examination frequency is one year and the validity of this document is one year.

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