

伦理审查批件

ETHICAL REVIEW APPROVAL ,BEIJING JISHUITAN HOSPITAL,
CAPITAL MEDICAL UNIVERSITY

伦理批件号 Approval No. of Ethics Committee: 积伦[K2025]第[018]号-00

项目名称 Name of Project	肌少症潜在治疗靶点筛选及机制探索		
申办者/项目来源 Sponsor	北京市属医学科研院所公益发展改革试点项目		
本中心研究者/研究项目负责人 Principal investigator	刘亚军		
审查类别 Review Type	复审 Resubmission	审查方式	☐ 会议审查 Meeting ☐ 紧急会议审查 Emergency meeting ☒ 简易程序审查 Expedited
会议日期 ¹ Meeting Date		会议地点 ¹ Meeting Place	
审查文件（含版本号和版本日期）The documents for review(including version No. and version date) : 1. 复审申请表; 2. 复审修改说明; 3. 知情同意书: 版本号 IMAT-02, 日期 2025 年 01 月 21 日。			
伦理审查委员会对该临床研究的审查结果 Review result: 同意 Approval			
本批件有效期 Validation: 批准日期 Approval Date: 2025 年 02 月 12 日 失效日期 Expiration Date: 2026 年 02 月 11 日			
该临床研究是否需要定期跟踪审查? If continue review needed? ☐ 否 No ☒ 是 Yes, 定期跟踪审查频率为 The frequency of continue review: ☐ 3 个月 3 months ☐ 6 个月 6 months ☒ 12 个月 12 months ☐ 其它（详细说明）: other(comments) 说明: 根据实际进展情况, 伦理审查委员会有权改变跟踪审查频率。 请研究者/研究项目负责人根据跟踪审查频率, 按时向伦理审查委员会递交定期/年度			



报告。

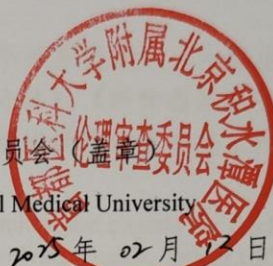
The Ethics Committee has the right to change the frequency of continue review according to the actual situation. Please submit the Progress Report to the Ethics Committee according to the frequency of continue review.

如果研究者/研究项目负责人或申办者对伦理审查委员会的审查结果有疑问或需要申诉, 请联络医院伦理审查委员会, 并提交书面申诉意见, 详细说明申诉理由。

Please contact and submit a written appeal proposal to the EC office if there is any complain or question about the EC review result, and describes the reason of appeal in details.

主任委员 (或被授权的副主任委员/委员) 签名 Signature of the Chair(or the authorized vice-chair/EC member):

首都医科大学附属北京积水潭医院伦理审查委员会 (盖章)
Ethics Committee(seal)of Beijing Jishuitan Hospital, Capital Medical University



Year month day

说明:

1. 请按照 GCP 原则和伦理审查委员会批准的文件开展研究, 保护受试者的健康与权益。
Please carry out the research in accordance with Good Clinical Practice and documents approved by the Ethics committee to protect the health and rights of the subjects.

2. 凡涉及人类遗传资源管理或者国家规定必须经有关部门审批的项目, 均需在执行前向有关部门申报并获得批准。

All projects involving the management of human genetic resources or which must be approved by the relevant authorities as stipulated by the State shall be reported to and approved by the relevant authorities before implementation.

3. 研究过程中, 对已批准的研究方案、知情同意书 (如有)、招募材料 (如有) 等的任何修改以及研究者/研究项目负责人的变更, 请提交修正案审查申请, 均须得到伦理审查委员会审查批准后方可实施。

Any revisions of previous approved research protocol, Informed Consent Form, recruitment materials, et al. and any change of the principal investigators, please submit a review application for the amendment and get re-approval before implementation during the research process.

4. 本中心发生的严重不良事件或影响受试者安全或权益的事件需在向监管部门上报的同时向伦理审查委员会作书面报告 (药物临床试验仅报可疑且非预期严重不良反应), 伦理委员会有权对其评估做出新的决定。

The Serious Adverse Events or accidents affected the subject's safety or welfare occurred in this centre shall be reported timely in writing to the Ethics Committee (Only SUSAR should be reported to EC for new drug clinical trials).

5. 本中心发生偏离方案时, 请及时提交偏离方案报告。

Please report the Protocol Deviations /Violations occurred on this site to EC in time.

6. 无论研究开始与否, 请按照伦理审查委员会规定的跟踪审查频率, 在截止日期前 1 个月提交研究进展报告。

A progress report should be submitted one month prior to the due date according to the frequency of continue review prescribed by the Ethics committee regardless whether the research has been initiated or not. 7. 暂停或提前终止研究, 请及时提交暂停/终止研究报告。 Please submit the suspension/termination report in time if the research is suspended or terminated in advance. 8. 完成临床研究, 请提交研究完成报告。 Please submit the research completion report in time. 9. 请在批件有效期内开展试验/研究, 逾期未开展的, 本伦理批件失效。 Please conduct the research within the approval period. 10. 伦理批件失效后的临床项目, 再次开展时, 需重新伦理审查。 The approval should be renewed if expired.	
声明 Declaration: 本伦理审查委员会的组成及工作程序符合《赫尔辛基宣言》、《人体生物医学研究国际道德指南》、《涉及人的生物医学研究伦理审查办法》、《药物临床试验质量管理规范》、《医疗器械临床试验质量管理规范》和《药物临床试验伦理审查工作指导原则》等国际伦理原则及我国相关规章和指导原则要求。 The composition and process program of this Ethics Committee are eligible for Declaration of Helsinki , Regulation for ethical review of biomedical research involving Human Beings, CIOMS, Good Clinical Practice, Guideline for Ethical Review of Drug Clinical Trials and relevant laws and regulations. 伦理办公室 Contact information of Ethics Committee: 地址 Address: 首都医科大学附属北京积水潭医院新街口院区北楼四层, 北京市西城区新街口东街 31 号。4th floor, North-Building, 31 Xinjiekou East Street, Xicheng District , Beijing 邮箱 E-mail: ecoffice@jst-hosp.com.cn 联系人 Contact: 科研项目/新技术项目 For Clinical research/ New medical technology 王娜 Wang Na 电话 Tel 010-58517080; 临床试验 For Clinical trials 林海琪 Lin Haiqi 电话 Tel 010-58517216。	
备注	无

注: “1” 适用于会议审查和紧急会议审查

“1”: Applicable to meeting and emergency meeting

