

Ethics Approval Document

FC AF-06-01.0

Review Opinion

Medical Ethics Committee, Affiliated Hospital of Sichuan Vocational College of Nursing
(The Third People's Hospital of Sichuan Province)
Review Opinion

File No.: KY-2025-0104

Review Date: February 25, 2025

Postal Code: 610100

Tel: 028-88438361

Address: Jinglong Road, Longquanyi District, Chengdu City, Sichuan Province

Basic Information			
Project Title	Study on Esketamine for Painless Gastrointestinal Endoscopy in Elderly Patients		
Project Code	KY-2025-0104	Principal Investigator	Wan Xiangqian
Funding Sponsor	Joint Clinical Scientific Research Fund of Chengdu Medical College		

Ethical Review	
Review Method	☐ Expedited Review ☒ Conference Review ☐ Emergency Conference Review
Review Category	☒ Initial Review ☐ Re-review ☐ Follow-up Review (select specific type

	if applicable): ☐ Protocol Amendment ☐ Protocol Violation ☐ Annual/Periodic Follow-up Review ☐ Study Suspension/Termination ☐ Serious Adverse Event ☐ Suspected Unexpected Serious Adverse Reaction ☐ Study Completion
Review Decision	☒ Approved ☐ Approval after Necessary Revisions ☐ Disapproved ☐ Suspend or Terminate Approved Research
Voting Result	Total committee members to attend: 17; 2 absent on leave; Actual attendees: 15. Voting results: 15 votes for approval, 0 votes for approval after necessary revisions, 0 votes for disapproval, 0 votes to suspend or terminate approved research. 0 recusals (the Principal Investigator recused and did not participate in voting).
Review Opinion	Approved.
Notes	1. The research team shall strictly abide by all ethical principles, relevant laws and regulations, and conduct clinical research in full accordance with the protocol approved by the Hospital Ethics Committee; 2. Any revisions to the study protocol, informed consent form, recruitment materials, investigator's brochure and other documents shall be submitted to the Ethics Committee for filing or review, and may only be implemented after obtaining official approval;

	3. In the event of Suspected Unexpected Serious Adverse Reactions (SUSARs) or serious adverse events during the study, relevant documents shall be promptly submitted in accordance with the hospital's Notice on Reporting Safety Information of Clinical Trial Projects; 4. Any protocol violations occurring during the research shall be reported via a protocol violation report without delay; 5. If the clinical study is suspended or terminated, a suspension/termination report shall be submitted in a timely manner; 6. Annual/periodic progress reports shall be submitted on schedule per the follow-up review frequency approved by the Ethics Committee; 7. A study completion report shall be promptly submitted upon the conclusion of the research project.
Attachments	None.

Issued by: Medical Ethics Committee,
 Affiliated Hospital of Sichuan Vocational College of Nursing
 (The Third People's Hospital of Sichuan Province)

四川护理职业学院附属医院（四川省第三人民医院）
医学伦理委员会审查意见

编号: KY-2025-0104

审查日期: 2025 年 2 月 25 日

地址: 四川省成都市龙泉驿区鲸龙路 121 号

邮编: 610100

电话: 028-88438361

基本信息			
项目名称	艾司氯胺酮对老年无痛胃肠镜检查的研究		
项目编号	KY-2025-0104	主要研究者	万向前
申办方	成都医学院联合临床科学研究基金		
伦理审查			
审查方式	☐ 快速审查 ☒ 会议审查 ☐ 紧急会议审查		
审查类别	☒ 初始审查 ☐ 复审 ☐ 跟踪审查 (若是, 选择以下具体种类) ☐ 修正案 ☐ 违背方案 ☐ 年度/定期跟踪 ☐ 暂停/终止研究 ☐ 严重不良事件 ☐ 可疑且非预期严重不良反应 ☐ 研究完成		
审查决定	☒ 同意 ☐ 必要的修改后同意 ☐ 不同意 ☐ 终止或者暂停已同意的研究		
投票结果	本次应到人数 17 人, 请假 2 人, 实到人数 15 人。 投票结果: 同意 15 票, 必要的修改后同意 0 票, 不同意 0 票, 终止或者暂停已同意的研究 0 票。回避 0 人 (为主要研究者, 未参与投票)。		
审查意见	同意。		
注意事项	1.请项目组严格遵循各项伦理原则及法律法规, 按本院伦理委员会同意的方案开展临床研究; 2.若研究方案、知情同意书、招募材料、研究者手册等文件修改, 须提交伦理委员会进行备案或审查, 经同意后方可开展; 3.若发生可疑且非预期严重不良反应或严重不良事件, 请及时按本中心《关于临床试验项目安全信息报告的通知》提交相关材料; 4.若研究过程中出现方案违背, 请及时提交方案违背报告; 5.若暂停或终止临床研究, 请及时提交暂停/终止研究报告; 6.研究项目须严格按照伦理委员会同意的跟踪审查频率, 及时提交年度/定期进展报告; 7.研究结束时, 须及时提交研究完成报告。		
附件	无。		

四川护理职业学院附属医院（四川省第三人民医院）

医学伦理委员会（盖章）

主任委员（签名）

