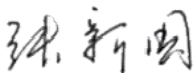
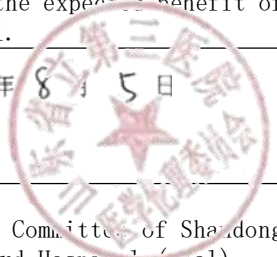


山东省立第三医院医学伦理委员会
伦理审查批件

伦理审查编号	KYLL-2024065		
项目名称	内镜下逆行阑尾炎治疗术(ERAT)与 eyeMax 子镜直视下逆行阑尾炎治疗术(SERAT)在治疗急性阑尾炎中的应用效果比较		
项目负责人及科室	消化内科 李晓沛		
申办单位	山东省立第三医院		
审查文件	☐ 项目申报书 ☐ 项目批文/任务书 ☐ 研究者手册 ☒ 研究方案 ☐ 知情同意书 ☐ 病例报告表 ☐ 项目负责人及参加人员列表与简历 ☐ 其他, 请说明:		
审查方式	☐ 会议审查 ☒ 快速审查 ☐ 跟踪审查		
审查决定	☒ 批准 ☐ 不批准 ☐ 修改后批准 ☐ 修改后再审 ☐ 暂停或终止		
审查意见	参加该项目的伦理委员会根据有关法律法规、赫尔辛基宣言等伦理原则已经对该项目提交的文件进行了审核, 认为研究者的资格、经验符合试验要求; 研究方案符合科学性和伦理原则的要求; 获得知情同意的方法适当; 受试者可能遭受的风险程度与研究预期的受益相比合适。同意按照研究方案开展研究。		
主任委员/ 副主任委员签字	张新国	日期	2024 年 8 月 5 日
山东省立第三医院医学伦理委员会 (盖章)			
注意: 1. 已批准项目应遵循已经伦理委员会批准的方案实施, 需符合 SFDA/GCP 和《赫尔辛基宣言》的原则。 2. 修改后再审的研究方案在提交复审方案前, 应按评审意见进行逐条修改并在修改处做出标记或说明, 修改后的方案连同初审意见一并递交伦理委员会申请复审。 3. 不批准和暂停或终止的研究方案, 申办者和研究者可就伦理委员会的意见和建议中提及的问题作书面申诉, 并陈述理由。 4. 研究过程中对研究方案和知情同意书等相关文件所作的任何修改, 均需得到伦理委员会审查同意后方可实施。 5. 本中心发生的严重不良事件或意外不良事件需在向伦理委员会作出书面通报, 伦理委员会有权根据其评估做出新的决定。 6. 请在跟踪审查前一个月向医学伦理委员会提交跟踪审查报告, 完成临床研究的项目, 须向伦理委员会提交结题报告。			

Approval letter of medical Ethics Committee of Shandong Provincial Third Hospital

Ethical review number	KYLL-2024065		
project name	The effect of endoscopic retrograde appendicitis (ERAT) and eyeMax (SERAT) in the treatment of acute appendicitis		
The Project leader and the department	Li Xiaopei, Departemnt of Gastroenterology		
Bid unit	Shandong Provincial Third Hospital		
audit-review file	☐ project declaration ☐ Project approval / task statement Investigator's manual ☒ study protocol ☐ informed consent ☐ case report form ☐ List of project leaders and participants and resumes. ☐ Other words, please explain:		
Review method	☐ Conference Review ☒ Quick Review Oral tracking review		
Review decision	☒ Approval ☐ Don't approved ☐ After the approval of the revision of ☐ The retrial mouth suspended or terminated		
Review opinions	The ethics committee participating in the project has reviewed the documents submitted by the project in accordance with the relevant laws and regulations, Declaration of Helsinki and concluded that the qualifications and experience of the investigator meet the requirements of scientific and ethical principles; the method of obtaining informed consent is appropriate: the wind that the subject may suffer The level of risk is appropriate compared to the expected benefit of the study. Agreed to follow the study protocol.		
chairman / Signature of the vice-chairman committee member		date	2024 年 8 月 5 日 
Medical Ethics Committee of Shandong Provincial Third Hospital (Seal)			

pay attention to:

- 1 Approved projects shall be implemented following the EC-approved protocol and shall comply with the principles of SFDA / GCP and the Declaration of Helsinki.
2. Before submitting the revised research plan for the review plan, it shall be revised one by one according to the review opinions and marked or explained in the review department. The revised plan shall be submitted to the Ethics Committee for review together with the preliminary review opinions.
3. For the study protocol not approved, suspended or terminated, the sponsor and the investigator may appeal in writing and justify the issues mentioned in the opinions and recommendations of the Ethics Committee
4. Any modification to the study protocol, informed consent form and other relevant documents during the study shall be reviewed and approved by the Ethics Committee.
5. Any serious adverse events or unexpected adverse events of the Center shall be notified in writing to the Ethics Committee, which has the right to make new decisions based on its evaluation.
6. Please submit the follow-up review report to the Medical Ethics Committee one month before the follow-up review. If the clinical research project is completed, the concluding report should be submitted to the Ethics Committee.