

其他:

无

伦理委员会意见函（同意）有效期 The Approval Period of EC Decisions Letter (Approval):
意见函（同意）有效期为批准之日起一年内有效，超过一年未启动该意见函（同意）自动失效。
If the trial/research is not initiated in 1 year, the trial/research needs to be reviewed again.

伦理委员会意见函（同意）的有效期指的是自伦理意见函（同意）之日起在多长时间之内开展试验/研究该伦理意见函有效。如果在伦理委员会意见函（同意）的有效期内没有开展试验/研究，则需要重新申请伦理审查。只要在伦理委员会意见函（同意）的有效期内开展了试验/研究，则本伦理委员会意见函（同意）有效。
The approval period of EC approval certificate means that a period of time in which the trial/research is initiated the EC approval certificate is effective from the approval date. If the trial/research is not initiated in the approval period, the trial/research needs to be reviewed again. If the trial/research is initiated in the approval period, this approval certificate is effective.

该研究进行是否将接受伦理委员会的跟踪审查（适用于初始审查）？

Will the research process accept follow-up review of the Ethics Committee (applicable for initial review)?

☐ 否 No

☒ 是 Yes,

定期/年度跟踪审查频率为 The frequency of regular review:

☐ 3 个月 3 months

☐ 6 个月 6 months

☒ 12 个月 12 months

☐ 其它 others (详细说明 specify): months

但伦理委员会会有根据实际进展情况改变跟踪审查频率的权利。

But the Ethics Committee has the right to change the frequency of follow-up review according to the actual progress.

请根据跟踪审查频率，按时向伦理委员会递交定期/年度报告。

Please submit the progress report to the Ethics Committee according to the continuing review frequency.

主任委员/授权者签名:

Signature of the Chair (or the authorized vice-chair/ EC member):

医学伦理委员会（盖章）:

Ethics Committee (seal):

年月日 2022-2-24

Year Month date

地址: 北京市海淀区复兴路 28 号邮编: 100853

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中国人民解放军总医院医学伦理委员会
Ethics Committee Of Chinese PLA General Hospital

临床科研项目意见函

Decisions Letter for Scientific Research Projects

伦审第 S2021-645-01 号

Approval No. of Ethics Committee

项目 信息 Project Information	项目名称 ProjectName	中文: 超级微创经乳头胆管取石术与内镜下括约肌切开术去除胆总管结石的有效性与安全性比较: 一项倾向性评分匹配研究 英文: Super minimally invasive lithotomy and endoscopic sphincterotomy for removal of bile duct stones :A propensity-matched analysis		
	课题来源 Project Source	研究者自发课题		
	研究类型 Project Type	前瞻性干预性临床研究		
	课题编号 ProjectNo:	2021-645	起止时间 Starting and Ending Times	2022/01/01- 2022/12/31
	科室 Office	消化内科	主要研究者 Principal Investigator	令狐恩强
	职称 Job Title	教授	联系电话 Contact number	010-68154653/13501233558
	审查类别 Review Type	初始审查 Initial Review		
审查方式 Review Approach	会议审查 Convened EC Conference			
审查日期 Date	2022/02/24	审查地点 Meeting Place	国际会议中心第五会议室	
审查文件及递交文件(含版本号和版本日期)清单见附件: Please find attached list of the documents for review and The other documents submitted this time (including version No. and version date)				
伦理委员会对该试验/研究的审查结果如下: The review result on the trial/research by the Ethics Committee is as follows: 同意 Approval				
具体意见(The details of the comments): 关于研究方案: 无 关于知情同意书: 无 关于招募广告: 无				

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