

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

临床科研项目意见函

Decisions Letter for Scientific Research Projects

伦审第 S2021-415-01 号

Approval No. of Ethics Committee

|  |                        |  |                                   |                           |
|--|------------------------|--|-----------------------------------|---------------------------|
| 项目<br>信息<br>Project<br>Information   | 项目名称<br>Project Name   | 中文: 电磁导航辅助 ERCP 插管初探   |                                   |                           |
|  |                        | 英文: Preliminary study on ERCP intubation aided by electromagnetic navigation |                                   |                           |
|  | 课题来源<br>Project Source | 研究者自发课题  |                                   |                           |
|  | 研究类型<br>Project Type   | 观察性临床研究  |                                   |                           |
|  | 课题编号<br>Project No:    | 2021-415   | 起止时间<br>Starting and Ending Times | 2021/07/01-<br>2022/07/01 |
|  | 科室<br>Office           | 消化内科   | 主要研究者<br>Principal Investigator   | 李明阳                       |
|  | 职称<br>Job Title        | 主任医师   | 联系电话<br>Contact number            | -                         |
| 审查类别<br>Review Type  |                        | 初始审查 Initial Review  |                                   |                           |
| 审查方式<br>Review Approach  |                        | 会议审查 Convened EC Conference  |                                   |                           |
| 审查日期<br>Date   |                        | 2021/07/29   | 审查地点<br>Meeting Place             | 综合医疗楼七层会议室                |
| <p>审查文件及递交文件(含版本号和版本日期)清单见附件:</p> <p>Please find attached list of the documents for review and The other documents submitted thistime (including version No. and version date)</p> |                        |  |                                   |                           |
| <p>伦理委员会对该试验/研究的审查结果如下:</p> <p>The review result on the trial/research by the Ethics Committee is as follows:</p> <p><b>同意 Approval</b></p>  |                        |  |                                   |                           |
| <p><b>具体意见(The details of the comments):</b></p> <p>关于研究方案:<br/>无</p> <p>关于知情同意书:<br/>无</p> <p>关于招募广告:<br/>无</p>   |                        |  |                                   |                           |

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)

2021 年 12 月 29 日  
Year Month date