

中国人民解放军总医院医学伦理委员会

Ethics Committee Of Chinese PLA General Hospital

临床科研项目意见书

Decisions Letter for Scientific Research Projects

伦审第 S2021-271-01 号

Approval No. of Ethics Committee

项目信息 Project Information	项目名称 Project Name	中文: 肿块型肝内胆管癌手术治疗预后及相关因素分析 英文: Analysis of prognosis and related factors of surgical treatment of mass-forming intrahepatic cholangiocarcinoma		
	课题来源 Project Source	研究者自发课题		
	研究类型 Project Type	观察性临床研究		
	课题编号 Project No:	2021-271	起止时间 Starting and Ending Times	2021/03/01 - 2021/06/01
科室 Office	科室 Office	肝胆外科		
	职称 Job Title	主任医师		
	联系电话 Contact number	-		
审查类别 Review Type	初始审查 Initial Review			
审查方式 Review Approach	快速审查 Expedited Review			
审查日期 Date	2021/07/29	审查地点 Meeting Place		-
审查文件及递交文件(含版本号和本日期)清单见附件: Please find attached list of the documents for review and The other documents submitted thistime (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				

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)

2021 年 04 月 29 日
Year Month date



注意 Note:

1. 本伦理委员会批准的项目为涉及人体的生物医学研究, 必须严格按照所批版本的研究方案和知情同意书开展研究, 并应遵循 NMPA/GCP 和《赫尔辛基宣言》的原则。

The "Approval" trial/research shall be implemented following the protocol approved by the Ethic Committee, and conforms to the principles of NMPA/GCP and Declaration of Helsinki.

2. 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, 均须得到伦理委员会审查同意后后方可实施。

During the research process, any revisions made to the documents related to the protocol and Informed Consent Form can't be implemented before obtaining the approval from the Ethics Committee.

3. 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 NMPA 上报的同时向伦理委员会作书面报告, 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 while reporting to NMPA, because the Ethics Committee has the right to make new decision on its evaluation.

4. 凡是涉及人类遗传资源出口或者按照国家规定必须经有关部门专项审批的内容, 均需在项目执行前向有关部门申报并获得批准, 本意见函(同意)自获批之后生效。

The trial /research involving the export of human genetic resources or special examination should be approved by the related departments before the trial /research is initiated.

5. 请在意见函(同意)有效期内开展试验/研究, 逾期未开展的, 本伦理意见函(同意)失效;

Please conduct the trial/research within the approval period, otherwise the approval certificate of ethical review is expired.

6. 伦理意见函(同意)失效后的试验/研究, 再次开展时, 需重新伦理审查。

The trial/research whose the approval certificate of ethical review is expired should be reviewed again.

声明 Declaration:

本伦理委员会的组成及工作程序符合《药物临床试验质量管理规范》、《赫尔辛基宣言》、《药物临床试验伦理审查工作指导原则》、《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》等相关法律法规的要求。

The composition and process program of this Ethics Committee are eligible for 《Good Clinical Practice》, 《Declaration of Helsinki》, 《Guideline for Ethical Review of Drug Clinical Trials》, 《International Ethical Guidelines for Biomedical Research Involving Human Subjects》, 《Regulations for ethical review of biomedical research involving human (National)》 and relevant laws and regulations.

附件:

递交伦理审查文件清单

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1. 初始审查申请表
2. 研究方案 (版本号: 1.0 版本日期: 2021/01/30)
3. 知情同意书 (版本号: 1.0 版本日期: 2021/03/03)
4. 病例报告表
5. 研究者经济利益声明
6. 主要研究者简历