

北京医院医学伦理委员会  
Ethics Committee Of Beijing Hospital  
临床科研审批件

APPROVAL CERTIFICATE OF ETHICAL REVIEW

伦审第 S2021-110-20号  
Approval No. of Ethics Committee

项目 信息 Project Information	项目名称 Project Name	中文: 进展期 HC 患者采用肝动脉重建对患者疾病预后的影响 英文: Effect of hepatic arterial reconstruction in patients with progressive HC		
	课题来源 Project Source	国际合作课题 <input type="checkbox"/> 国家级科研课题 <input type="checkbox"/> 军队科研课题 <input type="checkbox"/> 军民融合课题 <input type="checkbox"/> 北京市科研课题 <input type="checkbox"/> 医院科研课题 <input type="checkbox"/> 研究者自发课题 <input checked="" type="checkbox"/> 其他 <input type="checkbox"/>		
	课题编号 Project No.	-	起止时间 Starting and Ending Times	2015 年 2 月~2018 年 6 月
	科室 Office	影像与核医学	课题负责人 Principal Investigator	李元明
	职称 Job Title	副主任医师	联系电话 Contact Number	13718678135
	审查日期 Date	2021 年 3 月	审查地点 Meeting Place	NA
审查类别 Review Type		<input checked="" type="checkbox"/> 初始审查 Initial Review <input type="checkbox"/> 初始审查复审 Initial Review Resubmission <input type="checkbox"/> 修正案审查 Amendment Review <input type="checkbox"/> 修正案审查复审 Amendment Review Resubmission <input type="checkbox"/> 其他 Other:		
审查方式 Review Approach		<input type="checkbox"/> 紧急会议审查 Emergency Convened EC Conference <input type="checkbox"/> 会议审查 Convened EC Conference <input checked="" type="checkbox"/> 快速审查 Expedited Review		
1. 方案: 版本号: V1.0 版本日期: 2021 年 3 月 12 日				
此次伦理审查递交的其他文件(含版本号和版本日期)如下 The other documents submitted this time( including version No. and version date) are as follows: 1. 初始审查申请表 2. 研究经济利益声明 3. 研究者简历 4. 免除知情同意书申请表				

地址: 北京市东城区东单大华路 1 号 邮编: 100730



<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>同意 Approval</p>
<p>伦理委员会批件有效期 The Approval Period of EC Approval Certificate:</p> <p>批件有效期为批准之日起一年内有效, 超过一年未启动该批件自动失效。</p> <p>If the trial/research is not initiated in 1 year, the trial/research needs to be reviewed again.</p> <p>伦理委员会批件的有效期限指的是自伦理批准之日起在多长时间之内开展试验研究该伦理批件有效。如果在伦理委员会批件的有效期限内没有开展试验/研究, 则需要重新申请伦理审查。只要在伦理委员会批件的有效期限内开展了试验/研究, 则本伦理委员会批件有效。</p> <p>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.</p>
<p>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) ?</p> <p>Will the research process accept follow-up review of the Ethics Committee (applicable for initial review) ? ?</p> <p><input type="checkbox"/> 否 No</p> <p><input checked="" type="checkbox"/> 是 Yes,</p> <p>定期/年度跟踪审查频率为 The frequency of regular review:</p> <p><input type="checkbox"/> 3 个月 3months</p> <p><input type="checkbox"/> 6 个月 6months</p> <p><input checked="" type="checkbox"/> 12 个月 12months</p> <p><input type="checkbox"/> 其它 others</p> <p>(详细说明 specify) _____</p> <p>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。</p> <p>But the Ethics Committee has the right to change the frequency of follow-up review according to the actual progress.</p> <p>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。</p> <p>Please submit the progress report to the Ethics Committee according to the continuing review frequency.</p>
<p>是否需要调整定期/年度跟踪审查频率 (适用于跟踪审查) ? Does it need to change the regular review frequency (applicable for tracking review) ?</p> <p><input checked="" type="checkbox"/> 否 No</p> <p><input type="checkbox"/> 是 Yes,</p> <p>调整后的定期/年度跟踪审查频率为 The frequency of regular review revised:</p> <p><input type="checkbox"/> 3 个月 3months</p> <p><input type="checkbox"/> 6 个月 6months</p> <p><input type="checkbox"/> 12 个月 12months</p> <p><input type="checkbox"/> 其它 others (详细说明 specify) _____</p>
<p>如果主要研究者对 EC 的审查结果有疑问, 需要申诉, 请联络医院伦理委员会, 并提交书面申诉意见, 详细说明申诉理由。</p> <p>If the PI has some complains about the EC review result and needs to appeal against the decision, please contacts the hospital's EC, and submits a written appeal proposal, and describes the reason of appeal in details.</p>

地址: 北京市东城区东单大华路 1 号      邮编: 100730



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

医学伦理委员会 (盖章)

Ethics Committee (seal)

Year Month day

11100000185482

3月19日

**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，必须严格按照所批准版本的研究方案和知情同意书开展研究，并应遵循 NMP/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 CFDA/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方可实施。

During the research procs, any revisions made to the documents relate in 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' safety or welfare occurred in this Centre shall be reported timely in writing o the Ethics Committee while reporting to NMPA, because the Ethics Committee has the right to make new decision on its evaluation.

4. 见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，本批件自获批之后生效。

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. 请在批件有效期内开展试验/研究，逾期未开展的，本伦理批件失效；Please conduct the trial/research with in the approval period, otherwise the approval certificate of ethical review is expired.

6. 伦理批件失效后的试验/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.