

中国人民解放军总医院医学伦理委员会
Ethics Committee of Chinese PLA General Hospital
临床科研课题审批件
APPROVAL CERTIFICATE OF ETHICAL REVIEW

伦审第 S2021-512-032
Approval No. of Ethics Committee

项目 信息 Project Information	项目名称 Project Name	中文：载药微球 TACE 和传统 TACE 治疗中晚期肝癌的短期效果评价 英文：Evaluation of short-term effects of drug-loaded microspheres TACE and traditional TACE in the treatment of advanced liver cancer		
	课题来源 Project Source	国际合作课题 <input type="checkbox"/> 国家级科研课题 <input checked="" 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 type="checkbox"/> 其他 <input type="checkbox"/>		
	课题编号 Project No.	2016YFC0103908	起止时间 Starting and Ending Times	2017 年 01 月~2019 年 10 月
	科室 Office	核医学科	课题负责人 Principal Investigator	叶挺
	职称 Job Title	主治医师	联系电话 Contact Number	010-66937764
	审查日期 Date		审查地点 Meeting Place	
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：2020 年 7 月 25 日				
2. 免除知情同意书申请				
此次伦理审查递交的其他文件(含版本号 and 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				
伦理委员会对该试验/研究的审查结果如下:				

地址：北京市海淀区复兴路 28 号邮编：100853 联系人：曹江电话：010-66937166

<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: 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>但伦理委员会会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 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>

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.

Signature of the Chair (or the authorized vice-chair/EC member):
汪爱琴
2021年5月12日
Year Month day

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 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 NXMPA 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.