

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 S2020-371-01 号

Approval No. of Ethics Committee

|   |                        |   |                                   |                      |
|---|------------------------|---|-----------------------------------|----------------------|
| 项目<br>信息<br>Project<br>Information  | 项目名称<br>Project Name   | 中文: 股骨头骨坏死血流及病理结构改变特征研究<br>英文: Study on the characteristics of Blood flow and pathological changes of osteonecrosis of femoral head   |                                   |                      |
|   | 课题来源<br>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"/><br>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<br>Project No.    | 81972047  | 起止时间<br>Starting and Ending Times | 2022.11-2023.11      |
|   | 科室<br>Office           | 骨科  | 课题负责人<br>Principal Investigator   | 彭江                   |
|   | 职称<br>Job Title        | 研究员   | 联系电话<br>Contact Number            | <input type="text"/> |
| 审查日期<br>Date  |                        | 2022.11   | 审查地点<br>Meeting Place             | NA                   |
| 审查类别<br>Review Type   |                        | <input checked="" type="checkbox"/> 初始审查 Initial Review<br><input type="checkbox"/> 初始审查复审 Initial Review Resubmission<br><input type="checkbox"/> 修正案审查 Amendment Review<br><input type="checkbox"/> 修正案审查复审 Amendment Review Resubmission<br><input type="checkbox"/> 其他 Other: |                                   |                      |
| 审查方式<br>Review Approach   |                        | <input type="checkbox"/> 紧急会议审查 Emergency Convened EC Conference<br><input type="checkbox"/> 会议审查 Convened EC Conference<br><input checked="" type="checkbox"/> 快速审查 Expedited Review   |                                   |                      |
| 批准文件(含版本号 and 版本日期): The documents for initial review (including version No. and version date):<br>1. 方案 (版本号: V1.0 版本日期: 2020.9.30 )<br>2. 知情同意书 (版本号: V1.0 版本日期: 2020.9.30 )  |                        |   |                                   |                      |
| 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:<br>1. 研究者简历<br>2. 研究者手册 (版本号: 版本日期: )<br>3. 病例报告表 (版本号: V1.0 版本日期: 2020.9.30 )<br>4. 研究者经济利益声明表 |                        |   |                                   |                      |
| 伦理委员会对该试验/研究的审查结果如下:<br>The review result on the trial/research by the Ethics Committee is as follows:<br>同意 Approval   |                        |   |                                   |                      |

地址: 北京市海淀区复兴路 28 号 邮编: 100853

联系人: 曹江 电话:

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。

If the trial/research is not initiated in 1 year, the trial/research needs to be reviewed again.

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。

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) \_\_\_\_\_

但伦理委员会将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.

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)?

☒ 否 No

☐ 是 Yes,

调整后的定期/年度跟踪审查频率为 The frequency of regular review revised:

☐ 3 个月 3 months

☐ 6 个月 6 months

☐ 12 个月 12 months

☐ 其它others (详细说明specify) \_\_\_\_\_

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。

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.

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):

2022年11月26日  
Year Month date

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