尊敬的教授 Dear professor：金荣华

您提交的试验/研究经我院伦理委员会审查的结果如下：

The trial/research submitted by you has been reviewed by our Ethics Committee and the result is as following:

会议编号/日期 Meeting No./Date	2020.01.30	会议地点 Meeting Place	北京佑安医院B楼八层会议室
审查类别 Review Type	初始审查 Initial Review	审查方式 Review Approach	紧急会议审查 Emergency Convened EC Conference
本中心伦理存档编号 Ethics Committee archiving No.	LL-2020-011-K		
伦理委员会批件号 Approval No. of Ethics Committee	京佑科伦字[2020]006号		
试验/研究项目名称 Name of trial/research	磷酸氯喹治疗2019新型冠状病毒感染肺炎的临床试验		
申办者 Sponsor	中国人民解放军军事科学院军事医学研究院		
主要研究者 Principal Investigator	金荣华		
参会委员 Attending EC members	孙桂珍、林栋栋、孟庆华、平春霞、裴智娟、王咏梅、张彤、李筱永、郑素军、胡中杰、闻军		
未参与评审的委员（晚到、中途退出等） EC member who do not review this	无		

she/he comes to work late or leave early	
回避 EC 委员 EC members who shy away from the project review	无 No

批准文件（含版本号和版本日期）如下 The documents for review (including version No. and version date) are as follows:

1、研究方案 版本号：1.2 版，版本日期：2020 年 01 月 30 日

2、知情同意书 版本号：1.2 版，版本日期：2020 年 01 月 30 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:

病例报告表（版本号：1.2 版，2020 年 01 月 30 日）等

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

伦理委员会批件有效期 The Approval Period of EC Approval Certificate:

本批件批准日期 Approval Date: 2020.01.30 ;

有效期 Approval Period: 12 个月 ;

本批件失效日期 Expire Date: 2021.01.29 。

伦理委员会批件的有效期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)??

是 Yes, 定期/年度跟踪审查频率为 The frequency of regular review：6 个月 months
但是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。

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.

伦理委员会联系方式 Contact information of Ethics Committee:	010-83997028 010-83997022

主任委员（或被授权的副主任委员/委员）签名：
Signature of the Chair（or the authorized vice-chair/ EC member）：

首都医科大学附属北京佑安医院伦理委员会（盖章）：
Ethics Committee (seal) of Beijing YouAn Hospital,Capital Medical University:

2020 年 01 月 30 日
Year Month Day

注意 Note:
1.“同意”的试验/研究应遵循已经伦理委员会批准的方案执行，应符合 CFDA/GCP 和《赫尔辛基宣言》的原则。
The "Approval" trial/research shall be implemented following the protocol approved by the Ethics 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 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 CFDA 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 to the Ethics Committee while reporting to CFDA, because the Ethics Committee has the right to make new decision on its evaluation.

4、在开展试验/研究之前，请携带着“伦理审查批件”通知药物临床试验机构/科研处/医务处。 Please take the “APPROVAL CERTIFICATE OF ETHICAL REVIEW” to notify the Organization Office of Drug Clinical Trial/Scientific Research Division/Department of Medical Administration 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 within 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.

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