上海交通大学医学院附属第九人民医院医学伦理委员会

伦理审查批准函

Institutional Review Board of Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine

Ethnics Committee Approval Letter

声明：伦理委员会按照国家卫健委有关法规组成和工作，其审查和工作过程不受伦理委员会以外任何组织及个人的影响

Statement: The ethics committee is composed and operated in accordance with the relevant regulations of the National Health and Family Planning Commission and NMPA. The review and work process is not affected by any organizations or individuals other than the ethics committee.

批件号：SH9H-2022-T139-1

Approval No.:SH9H-2022-T139-1

审查日期 Date of review	2022 年 06 月 07 日
研究项目名称 Study Title	新冠疫苗保护效益和临床特征的回顾性研究 A retrospective study on the protective benefits of vaccine and clinical characteristics of COVID-19
审查会议地点 Meeting Location	/
申办者 Sponsor	感染科
研究单位 Research institutions	上海交通大学医学院附属第九人民医院
主要研究者 Principal investigator	许洁
伦理审查方式 Method of review	□会议审查 Full Board Review ■快速审查 Expedited Review　　第(1)次快速审查时间：2022-06-07
审查文件 Files of review	初始审查清单： 1.临床试验方案　　版本号：01，版本日期：2022 年 06 月 04 日 2.免知情同意申请 3.研究者简历

	4.研究者声明
审查意见 Opinions of review	1.经伦理委员会审查，同意该项临床研究。 This clinical study was approved by the ethics committee. 2.伦理委员会对该研究实施过程的持续跟踪审查： The institutional ethics committee conducts an annual/periodic follow-up review of the implementation of the study ■是/Yes　　□否 /No 审查频度为： Review frequency □3 个月/3 Months　　□6 个月/6 Months ■12 个月/12 Months　　□不改变/Keep it as it is 3.伦理委员会有权根据实际进展情况改变持续跟踪审查频度。 The ethics committee has the power to change the frequency of annual/periodic follow-up reviews based on actual progress. 4.自批准之日起一年内项目未启动，该批件自动失效。 If the project is not started within one year from the date of approval, the approval will automatically become invalid.
	主任或副主任委员签字： Chairman: 伦理委员会（盖章）2022.6.7 日期： Date：

注意：（请仔细阅读）

1.伦理委员会批准的项目为涉及人体的生物医学研究，必须严格按照所批最新版本的研究方案和知情同意书开展研究，并遵循国内相关法规指南要求。

2.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。

3.本批件可能用于其他中心伦理委员会参考，如果对审查存在不同意见，请及时与本伦理委员会沟通。

4.对已批准的研究方案、知情同意书等材料的任何修改及主要研究者更换等，须及时通知本

伦理委员会重新审查，获得批准后执行。

5.发生严重不良事件及影响研究风险受益比的非预期事件，须及时报告本机构伦理委员会。

6. 根据伦理委员会对年度/定期跟踪审查频度的意见，无论研究开始与否，请在年度/定期跟踪审查日到期前 1 个月提出年度/定期跟踪审查的申请。

7.发现不依从/违反方案情况须及时报告伦理委员会审查。

8.暂停/提前终止临床研究，请及时通知伦理委员会。

9.完成研究，须提交结题报告供伦理委员会审查。

Note :(Please read carefully)

1. The project approved by the ethics committee of this institution is biomedical research involving human beings, which must be carried out in strict accordance with the approved latest version of the research scheme and informed consent, and in accordance with the requirements of relevant domestic regulations and guidelines.

2. Anything involving the export of human genetic resources or subject to special examination should be approved by the relevant departments in accordance with state regulations. This situation shall be reported and approved by the relevant departments before the implementation of the project.

3. This approval may be used for the reference of other central ethics committees. If you have different opinions on the review of the program, please contact the ethics committee in time.

4. Any modification of the approved study protocol, informed consent and other materials such as the replacement of the principal investigator shall be notified in time. The ethics committee will re-examine the implementation.

5. Any serious adverse events or unexpected events that affect the study risk/benefit ratio shall be reported to the ethics committee of the institution in time.

6. According to the opinion of the ethics committee on the frequency of annual/periodic follow-up review, whether the study begins or not, please submits an application for annual/periodic follow-up review one month prior to the expiration of the annual/periodic follow-up review date.

7. Report any non-compliance/violation to the ethics committee for review in time.

8. Suspension/early termination of clinical research, please inform the ethics committee in time.

9. The study requires the submission of a final report for review by the ethics committee.

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