公　证　书

中华人民共和国

甘肃省永登县公证处

安阳市人民医院
医学伦理委员会伦理审查批件

伦理审查编号	KS-2024-05-15	伦理存档档案号	LW2024-021
名称	CliniLab: Aligning Agents for Multi-Departmental Clinical Diagnostics in the Real World		
主要研究者	Tengxiao Wu	研究科室	普外科
研究分类	科研和临床试验研究		
审查方式	快速审查	审查日期	2024 年 5 月 15 日
审查结果： 同意该研究项目在本院开展。			

审查意见：

遵循卫计委《涉及人的生物医学研究伦理审查办法（试行）》（2016）、SFDA《药物临床试验质量管理规范》（2003）、《医疗器械临床试验规定》（2004）、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究，并在研究过程中，最大程度地保护受试者的健康与权益。

在研究过程中，若变更主要研究者，对临床研究方案、知情同意书等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告。

请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；当出现任何可能显著影响研究进行或增加受试者危险的情况时，请申请人及时向伦委会提交书面报告。

试验纳入了不符合纳入标准或符合排除标准的受试者，符合终止试验规定而未让受试者退出试验，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背伦理原则与规范的情况，请申办者/监察员/研究者提交违背方案报告。

申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。

完成临床研究，请申请人提交研究完成报告。			
定期跟踪审查频率	12 个月	批件有效期至	2025 年 5 月 15 日
说明：研究需按照伦理委员会审查批准的方案和知情同意书进行。获得批件后在有效期内未启动或启动后未入组受试者，批件自动作废。			
安阳市人民医院伦理委员会（盖章）： 日 期：2024年5月15日			

公　证　书

（2024）甘兰永公字第20号

申请人：颜为骧，男，1999年1月8日出生，公民身份号码：622326199901080035，身份证住址：甘肃省天祝藏族自治县华藏寺镇祝贡南路37栋23号。

代理人：颜少鲁，男，1965年9月17日出生，公民身份号码：622326196509170032，住址：甘肃省天祝藏族自治县华藏寺镇祝贡南路37－23号。

公证事项：伦理审查批件

兹证明前面的复印件与安阳市人民医院医学伦理委员会于2024年5月15日出具的《安阳市人民医院医学伦理委员会伦理审查批件》的原件相符，原件属实。

中华人民共和国甘肃省永登县公证处

公证员 赵梅

登

2024年5月31日

公证处

IV50813110

Anyang People's Hospital

Ethics Review and Approval by Medical Ethics Committee

Ethics Review No.	KS-2024-05-15	Ethics Archive No.	LW2024-021
TITLE	Clini Lab: Aligning Agents for Multi-Departmental Clinical Diagnostics in the Real World		
Major Researcher	Tengxiao Wu	Research Department	General Surgery
Research Classification	Scientific Research and Clinical Trial Research		
Review Method	Quick Review	Date of Review	May 15, 2024
Result of Review: It is agreed that the research project can be carried out in Anyang People's Hospital.			

Review Comments:

Following the ethical principles listed in *Ethical Review Measures for Biomedical Research Involving Human Subjects (Trial)* (2016) issued by National Health Commission, *Good Clinical Practice* (2003) issued by SFDA, *Provisions for Clinical Trials of Medical Devices* (2004), WMA's *Declaration of Helsinki* and *International Ethical Guidelines for Health-related Research Involving Humans* published by CIOMS, after review, the Medical Ethics Committee agrees on carrying out this study in accordance with the approved clinical research protocol, informed consent, and recruitment materials, and during the study, the health and rights of subjects should be protected to the greatest extent.

During the study, if the major researcher is changed or any modification to the clinical study protocol or informed consent and so on is made, the application for amendment review is requested to be submitted.

If a serious adverse event occurs, the applicant is requested to submit a report on the serious adverse event in a timely manner.

Please adhere to the annual/periodic follow-up review frequency stipulated by the Medical Ethics Committee, the applicant should submit research progress report 1 month ahead of the deadline; If there is any situation that may significantly affect the progress of the study or increase the risk of the subjects, the applicant is requested to submit a written report to the Medical Ethics Committee in a timely manner.

If the trial involves subjects who didn't met the inclusion criteria or who met the exclusion criteria or subjects who met the requirements for termination of the trial but did not withdraw from the trial, or if subjects were given the wrong treatment or dose or given combined drugs prohibited by the protocol, etc., which did not follow the protocol to carry out the study, or if the trial may have a negative impact on the rights/health of the subjects and the scientific nature of the research and other violations of ethical principles and norms, the applicant/inspector/researcher is requested to submit a report on violation of principle.

For suspending clinical study or terminating it early, the applicant shall submit the report on suspension/termination of study in time.

IV50813106

When the clinical study is completed, the applicant is requested to submit a report regarding the completion of the study.			
Periodic Follow-up Review Frequency	12 months	Approval Valid until	May 15, 2025
Note: The study should be conducted in accordance with the protocol approved by the Medical Ethics Committee and the informed consent. If the trial is not activated within the validity period or subjects are not enrolled after obtaining the approval document, the approval document will be automatically invalidated.			
Medical Ethics Committee of Anyang People's Hospital: Medical Ethics Committee of Anyang People's Hospital (Seal) Date: May 15, 2024			

NOTARIAL CERTIFICATE

(2024) Gan Lan Yong Gong Zi, No. 20

Applicant: Weixiang Yan, male, born on Jan. 8, 1999, Citizen ID Card No.: 622326199901080035, Address on ID Card: No. 23, Building 37, South Zhugong Road, Huazangsi Town, Tianzhu Tibetan Autonomous County, Gansu Province.

Entrusted agent: Shaolu Yan, male, born on Sept. 17, 1965, Citizen ID Card No.: 622326196509170032, Address on ID Card: No. 37-23, South Zhugong Road, Huazangsi Town, Tianzhu Tibetan Autonomous County, Gansu Province.

Issue under notarization: Ethics Review and Approval

This is to certify that the original of *Ethics Review and Approval by Medical Ethics Committee of Anyang People's Hospital* issued by Medical Ethics Committee of Anyang People's Hospital on May 15, 2024 conforms to the foregoing photocopy, and that the original is authentic.

Yongdeng Notary Public Office, Gansu Province,
the People's Republic of China
Notary Public: Mei Zhao (Signet)
May 31, 2024

I V50813108

公证书核实联系电话：0931—6423834